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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

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FEDERAL ELECTION COMMISSION

11 CFR Part 4

[Notice 2024–13]

FOIA Improvement Act

AGENCY: Federal Election Commission.

ACTION: Interim final rule; request for comments.

SUMMARY: Congress enacted the FOIA Improvement Act of 2016, which amends the Freedom of Information Act, as relevant here, to require Federal agencies to change how certain records and documents are made available for public inspection. The Commission is amending its regulations to implement this statutory mandate. The Commission is accepting comments on these revisions to its regulations, and any comments received may be addressed in a subsequent rulemaking document.

DATES: Effective July 1, 2024. Comments must be received on or before June 3, 2024.

ADDRESSES: All comments should be addressed to Ms. Amy L. Rothstein, Assistant General Counsel, and must be submitted in either written or electronic form. Commenters are encouraged to submit comments electronically via the Commission's website at *https://sers.fec.gov/fosers,* reference REG 2024–02. Alternatively, comments may be submitted in paper form addressed to the Federal Election Commission, Attn.: Ms. Amy L. Rothstein, Assistant General Counsel, 1050 First Street NE, Washington, DC.

Each commenter must provide, at a minimum, the commenter's first name, last name, city, and state. All properly submitted comments, including attachments, will become part of the public record, and the Commission will make comments available for public viewing on the Commission's website and in the Commission's Public Records Office. Accordingly, commenters should not provide in their comments any information that they do not wish to make public, such as a home street address, personal email address, date of birth, phone number, social security number, or driver's license number, or any information that is restricted from disclosure, such as trade secrets or commercial or financial information that is privileged or confidential.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Rothstein, Assistant General Counsel, Ms. Joanna Waldstreicher or Ms. Sarah Herman Peck, Attorneys, (202) 694–1650 or (800) 424–9530.

SUPPLEMENTARY INFORMATION:

A. Background

The FOIA Improvement Act of 2016 (the ''FOIA Improvement Act'') amends the Freedom of Information Act (''FOIA''), as relevant here, to require Federal agencies to change how certain records and documents are made available for public inspection.[1] In particular, the FOIA Improvement Act directs Federal agencies to make certain records available in electronic format for public inspection; prohibits, subject to exception, an agency from charging fees to a FOIA requester if the agency misses a deadline after receiving a FOIA request; requires agencies to notify FOIA requesters who have received adverse determinations about their right to seek dispute resolution services; prohibits agencies from withholding information requested under FOIA unless the agencies reasonably foresee that disclosure would harm an interest protected by a FOIA exemption or the disclosure is prohibited by law; requires agencies withholding information requested under FOIA to consider whether partial disclosure is possible; and eliminates an exemption from disclosure under FOIA of certain agency records created at least 25 years before the date of the FOIA request.[2] The FOIA Improvement Act also explicitly directs the head of each Federal agency to promulgate regulations to implement these changes to its FOIA practices.[3]

To implement the FOIA Improvement Act's mandates, the Commission is now amending 11 CFR 4.4 through 4.5 and 4.7 through 4.9, setting forth the Commission's obligations and procedures for disclosing documents under FOIA. Before final promulgation of any rules or regulations to carry out the provisions of the Federal Election Campaign Act, the Commission transmits the rules or regulations to the Speaker of the House of Representatives and the President of the Senate for a thirty-legislative-day review period.[4] The effective date of this final rule is July 1, 2024. The Commission welcomes public comment on this interim final rule and may address any comments received in a later rulemaking document.

The Commission is promulgating these amendments without advance notice or an opportunity for comment because they fall under the ''good cause'' exemption of the Administrative Procedure Act.[5] The Commission finds that notice and comment are unnecessary here because the changes are technical amendments to conform with explicit statutory requirements. Amending these regulatory provisions does not involve any exercise of discretion by the Commission. Moreover, because Congress has already enacted the changes to FOIA through the FOIA Improvement Act, the new ''administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' [6] For these reasons, the Commission is not required to publish a notice of proposed rulemaking to promulgate these regulatory provisions.

For the same reasons, these amendments fall within the ''good cause'' exception to the delayed effective date provisions of the Administrative Procedure Act and the Congressional Review Act.[7] Moreover, because this amendment is exempt from the notice and comment procedure of the Administrative Procedure Act under 5 U.S.C. 553(b), the Commission is not required to conduct a regulatory flexibility analysis under 5 U.S.C. 603 or 604.[8]

[1] Public Law 114–185, 130 Stat. 538 (2016).
[2] *Id.* sec. 2.
[3] *Id.* sec. 3.
[4] 52 U.S.C. 30111(d)(2).
[5] 5 U.S.C. 553(b)(B).
[6] *See Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (internal citation omitted).
[7] 5 U.S.C. 553(d)(3), 808(2).
[8] *See* 5 U.S.C. 601(2), 604(a).

B. Revisions to 11 CFR Part 4—Public Records and the Freedom of Information Act

Part 4 of the Commission regulations sets forth the Commission's public records obligations under FOIA. Section 4.4 requires the Commission to make specific categories of materials available for public inspection, subject to exceptions outlined in 11 CFR 4.5.[9] Section 4.7 specifies the framework for requesting access to Commission records, and the appeal process for denied requests is delineated in 11 CFR 4.8. Notice requirements for any associated fees is provided in 11 CFR 4.9. The Commission is amending each of these five sections within 11 CFR part 4 pursuant to the FOIA Improvement Act.

(i). Revisions to 11 CFR 4.4—Availability of Records

The Commission is amending 11 CFR 4.4(a) and (c) and adding new paragraph (h) to reflect new standards for the availability of certain records.

First, current 11 CFR 4.4(a) requires the Commission to make certain materials available for public inspection and copying. The Commission is amending paragraph (a) to provide that the Commission will make those materials available for public inspection in an electronic format.

Second, current 11 CFR 4.4(a)(4) requires the Commission to make available for public inspection copies of all records that have been released to any person under paragraph (a) and which the agency has determined have become or are likely to become the subject of subsequent requests. The Commission is amending paragraph (a)(4) to provide that the Commission will make available for public inspection copies of all records that have been released to any person under paragraph (a) three or more times or which the agency determines have become or are likely to become subject to subsequent requests.

Third, current 11 CFR 4.4(c) provides, in part, that the Commission must maintain and make available current indexes providing identifying information regarding any matter issued, adopted, or promulgated after April 15, 1975, as required by 5 U.S.C. 552(a)(2)(C) and (E). The Commission is amending paragraph (c) to provide that these indexes will be made available in an electronic format.

Lastly, the Commission is adding new 11 CFR 4.4(h) to provide that the Commission will withhold releasing information under § 4.4 only if the Commission reasonably foresees that disclosure would harm an interest protected by an exemption listed in 11 CFR 4.5(a) or disclosure is prohibited by law. New paragraph (h) also provides that, when the Commission determines full disclosure of a requested record is not possible, the Commission will consider whether partial disclosure is possible and will take reasonable steps necessary to segregate and release nonexempt information.

(ii). Revisions to 11 CFR 4.5—Categories of Exemptions

Current 11 CFR 4.5(a)(5) provides that no FOIA request will be denied release unless the record contains, or its disclosure would reveal, inter-agency or intra-agency memoranda or letters that would not be available by law to a party in litigation with the Commission. The Commission is amending this provision to specify that the exemption applies only to documents not available to a party other than an agency in litigation with the Commission, and that the deliberative process privilege will not apply to records created 25 years or more before the request date, consistent with the FOIA Improvement Act.

(iii). Revisions to 11 CFR 4.7—Requests for Records

The Commission is amending 11 CFR 4.7(c) and (h) and adding paragraph (j) to include new requirements for notifying requesters about the status of a request.

First, current 11 CFR 4.7(c) requires the Commission to determine, within twenty working days after receiving a request or granting an appeal, whether to comply with the request, unless in unusual circumstances the time is extended or subject to § 4.9(f)(3), which governs advance payments. The Commission is amending 11 CFR 4.7(c) to provide that the Commission will immediately notify the requester of the determination, the reasons therefore, and the requester's right to seek assistance from the Commission's FOIA Public Liaison and to seek dispute resolution services from the National Archives and Records Administration (''NARA''), Office of Government Information Services.

Second, current 11 CFR 4.7(h) provides that any person denied access to records by the Commission must be notified immediately, stating the reasons for the denial. The notice must also state that the person denied access to records may appeal the adverse determination to the Commission. The Commission is amending this paragraph to provide that the person denied access will be notified of that person's right to appeal within 90 days from the date of the adverse determination. Such notice also must state that the person denied access to records may seek dispute resolution services from the Commission's FOIA Public Liaison or NARA's Office of Government Information Services.

Finally, the Commission is adding 11 CFR 4.7(j) to explain the role of, and provide contact information for, the FOIA Public Liaison.

(iv). Revisions to 11 CFR 4.8—Mediation Services and Appeal of Denial

The Commission is amending 11 CFR 4.8 by adding paragraph (h), which will notify requesters that they may seek non-compulsory, non-binding mediation services to help resolve FOIA disputes. The Commission is also amending the heading of 11 CFR 4.8 to reflect the availability of such mediation services.

(v). Revisions to 11 CFR 4.9—Fees

Finally, the Commission is amending 11 CFR 4.9(a), which lists exceptions to fee charges. The Commission is adding paragraph (a)(5) to address time limits for compliance.

New 11 CFR 4.9(a)(5)(i) provides that the Commission will not charge a fee to any requester if the Commission does not comply with the time limits in 11 CFR 4.7(c) or 4.8(f).

New 11 CFR 4.9(a)(5)(ii) provides that a failure to comply with the time limits is excused for another ten days if the Commission has determined that unusual circumstances (as defined in 5 U.S.C. 552(a)(6)(B)(i) and 11 CFR 4.7(c)) apply and has provided timely written notice to the requester under 11 CFR 4.7(c). New 11 CFR 4.9(a)(5)(ii) further provides that the Commission may not assess any search or duplication fees if it fails to comply with the extended time period.

New 11 CFR 4.9(a)(5)(iii) describes the circumstances under which the Commission may charge search or duplication fees after determining that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request.

Finally, new 11 CFR 4.9(a)(5)(iv) provides that when a court has determined that exceptional circumstances exist, a failure to comply with the time limit shall be excused for the length of time provided by the court's order.

[9] Exempt documents include records that are classified, records that relate to internal personnel rules, records that are exempted by statute, records that contain trade secrets or commercial or financial information that is privileged or confidential, certain inter-agency or intra-agency documents, personnel and medical files, and certain records compiled for law enforcement purposes.

List of Subjects in 11 CFR Part 4

Freedom of information.

For the reasons set out in the preamble, the Federal Election Commission amends 11 CFR chapter I, as follows:

PART 4—PUBLIC RECORDS AND THE FREEDOM OF INFORMATION ACT

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 5 U.S.C. 552, as amended.

■ 2. Amend § 4.4 by revising paragraphs (a) introductory text, (a)(4) and (c), and adding paragraph (h) to read as follows:

§ 4.4 Availability of records.

(a) In accordance with 5 U.S.C. 552(a)(2), the Commission shall make the following materials available for public inspection in an electronic format:

* * * * *

(4) Copies of all records, regardless of form or format, which have been released to any person under this paragraph (a) and;

(i) Which, because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records, or

(ii) Which have been requested three or more times; and

* * * * *

(c) The Commission shall maintain and make available for public inspection in an electronic format current indexes and supplements providing identifying information regarding any matter issued, adopted, or promulgated after April 15, 1975, as required by 5 U.S.C. 552(a)(2)(C) and (E). These indexes and supplements shall be published and made available on at least a quarterly basis for public distribution unless the Commission determines by Notice in the **Federal Register** that publication would be unnecessary, impracticable, or not feasible due to budgetary considerations. Nevertheless, copies of any index or supplement shall be made available upon request at a cost not to exceed the direct cost of duplication.

* * * * *

(h) The Commission will withhold information under this section only if the Commission reasonably foresees that disclosure would harm an interest protected by an exemption described in § 4.5(a); or disclosure is prohibited by law. The Commission will consider whether partial disclosure of information is possible whenever it determines that full disclosure of a requested record is not possible, and the Commission will take reasonable steps necessary to segregate and release nonexempt information.

■ 3. Amend § 4.5 by revising paragraph (a)(5) to read as follows:

§ 4.5 Categories of exemptions.

(a) * * *

(5) Inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the Commission, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

* * * * *

■ 4. Amend § 4.7 by revising paragraphs (c) introductory text and (h) and adding paragraph (j) to read as follows:

§ 4.7 Requests for records.

* * * * *

(c) The Commission shall determine within twenty working days after receipt of a request, or twenty working days after an appeal is granted, whether to comply with such request, unless in unusual circumstances the time is extended or subject to § 4.9(f)(3), which governs advance payments. The Commission shall immediately notify the requester of such determination, the reasons therefor, and the right of the requester to seek assistance from the FOIA Public Liaison for the Commission and to seek dispute resolution services from the Office of Government Information Services. In the event the time is extended, the requester shall be notified of the reasons for the extension and the date on which a determination is expected to be made, but in no case shall the extended time exceed ten working days. An extension may be made if it is—

* * * * *

(h) Any person denied access to records by the Commission shall be notified immediately giving reasons therefor, and notified of the right of such person to appeal such adverse determination to the Commission within 90 days from the date of the adverse determination and the right of such person to seek dispute resolution services from the FOIA Public Liaison for the Commission or the Office of Government Information Services.

* * * * *

(j) The FOIA Public Liaison is responsible for reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes. The FOIA Public Liaison may be contacted at the address identified in the definition of ''Commission'' in § 1.2 of this chapter.

■ 5. Amend § 4.8 by revising the section heading and adding paragraph (h) to read as follows:

§ 4.8 Mediation services and appeal of denial.

* * * * *

(h) The National Archives and Records Administration (NARA), Office of Government Information Services (OGIS) offers non-compulsory, non-binding mediation services to help resolve FOIA disputes as a non-exclusive alternative to litigation. A requester may contact OGIS at: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001; email: *ogis@nara.gov*; telephone 202–741–5770; fax: 202–741–5769; online: *https://www.archives.gov/ogis.*

■ 6. Amend § 4.9 by adding paragraph (a)(5) to read as follows:

§ 4.9 Fees.

(a) * * *

(5) *Time limit for compliance.* (i) The Commission will not charge a fee under this section to any requester if the Commission does not comply with the time limits in § 4.7(c) or § 4.8(f).

(ii) If the Commission has determined that unusual circumstances (as defined in 5 U.S.C. 552(a)(6)(B)(iii) and § 4.7(c)(1) through (3)) apply and the Commission provided timely written notification to the requester in accordance with § 4.7(c), a failure to comply with the time limit is excused for an additional 10 days. If the Commission fails to comply with the extended time limit, the Commission may not assess any search fees or, where applicable, duplication fees.

(iii) If the Commission has determined that unusual circumstances apply and more than 5,000 pages are necessary to respond to the request, the Commission may charge search fees or, where applicable, duplication fees, if the Commission has provided timely written notification to the requester in accordance with § 4.7(c) and the Commission has discussed with the requester via written mail, electronic mail, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with § 4.7(d).

(iv) If a court has determined that exceptional circumstances exist, a failure to comply with the time limit

shall be excused for the length of time provided by the court order.

* * * * *

Dated: April 18, 2024.

On behalf of the Commission.

Sean J. Cooksey,

Chairman, Federal Election Commission.

[FR Doc. 2024–08700 Filed 5–1–24; 8:45 am]

BILLING CODE 6715–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

[Docket No. SBA–2023–0010]

RIN 3245–AH83

Microloan Program; Changes to the Microloan Program Under the Economic Aid To Hard-Hit Small Businesses, Nonprofits, and Venues Act

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Direct final rule.

SUMMARY: The U.S. Small Business Administration (SBA) is amending its Microloan Program regulations to reflect statutory changes to the Microloan Program contained in the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act. The changes increase the total amount an Intermediary may borrow under the Microloan Program per year and in aggregate, expand eligibility for Intermediaries to receive a bonus grant and add the necessary definitions, and revise the eligible base grant award amount for Intermediaries under certain circumstances. This direct final rule conforms the regulations to the Act by adopting the new statutory requirements without change.

DATES: This rule is effective June 17, 2024 without further action, unless significant adverse comment is received by June 3, 2024. If significant adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by docket number SBA–2023–0010, by any of the following methods:

(1) *Federal Rulemaking Portal: http://www.regulations.gov*, following the specific instructions for submitting comments;

(2) *Email: Daniel.Upham@sba.gov*; or

(3) *Mail/Hand Delivery/Courier:* Daniel Upham, Chief, Microenterprise Development Division, 409 3rd Street SW, 8th Floor, Washington, DC 20416.

SBA will post all comments on *http://www.regulations.gov*. If you wish to submit confidential business information (CBI) as defined in the User Notice at *http://www.regulations.gov*, please submit the information to Daniel Upham, Chief, Microenterprise Development Division, 409 3rd Street SW, 8th Floor, Washington, DC 20416. Highlight the information that you consider to be CBI and explain why you believe this information should be held confidential. SBA will review the information and make the final determination as to whether to publish the information.

FOR FURTHER INFORMATION CONTACT: Daniel Upham, Microenterprise Development Division, (202) 205–7001 or *Daniel.Upham@sba.gov*.

SUPPLEMENTARY INFORMATION:

A. General Information

The U.S. Small Business Administration (SBA) is amending its Microloan rules to reflect statutory changes from section 329 of the Economic Aid to Hard-Hit Small Businesses, Nonprofits, and Venues Act (Pub. L. 116–260), enacted December 27, 2020 (the Economic Aid Act). SBA's Microloan Program is authorized by section 7(m) of the Small Business Act, (15 U.S.C. 636(m)) and 13 CFR part 120, subpart G. The Microloan Program provides loans up to $50,000 to help small businesses and certain not-for-profit childcare centers start up and expand. SBA provides funds to specially designated intermediary lenders, which are nonprofit community-based organizations with experience in lending as well as management and technical assistance. These intermediaries administer the Microloan Program for eligible borrowers.

SBA is amending §§ 120.701, 120.706, and 120.712 to incorporate Microloan Program changes required by the Economic Aid Act. The specific regulatory changes are detailed below in the section-by-section analysis.

B. Section-by-Section Analysis

1. § 120.701 Definitions

Section 329 of the Economic Aid Act established two new definitions: ''Economically Distressed Area'' and ''Rural Area.'' To recognize these additions, the definitions for the Microloan Program are revised.

2. 120.706 What are the terms and conditions of an SBA loan to an Intermediary?

The Economic Aid Act permanently increased the maximum amount an Intermediary may borrow from SBA to $3,000,000 per year, with an aggregate outstanding limit of $7,000,000. The maximum amount an Intermediary may borrow during its first year of participation remains $750,000.

3. 120.712 How does an Intermediary get a grant to assist Microloan borrowers?

The Economic Aid Act provides a new minimum base grant amount of 25 percent of an Intermediary's total outstanding SBA loan balance applicable in fiscal years in which the amount appropriated for TA grants is sufficient to provide all Intermediaries with a grant equal to 25 percent or more of their total outstanding SBA loan balances. In these fiscal years, the maximum base grant amount is 30 percent of an Intermediary's total outstanding SBA loan balance. Intermediaries eligible for bonus grants may receive an additional grant for a total eligible maximum grant amount of 35 percent of the total outstanding SBA loan balance. SBA has revised paragraph (a) to reflect these statutory changes.

Currently, Intermediaries that maintain a portfolio of Microloans averaging $10,000 or less are eligible for a bonus grant equal to 5 percent of the Intermediary's total outstanding SBA loan balance. The Economic Aid Act expands eligibility for bonus grants to: (a) Intermediaries that provide not less than 25 percent of their Microloans to small businesses located in or owned by one or more residents of an economically distressed area and (b) Intermediaries with a Microloan portfolio of which at least 25 percent is serving rural areas. SBA has revised paragraph (c) to include these two additional bonus grant eligibility criteria.

C. Compliance With Executive Orders 12866, 12988, 13132, 13175, and 13563, the Congressional Review Act (5 U.S.C. 801–808), the Paperwork Reduction Act (44 U.S.C., Ch. 35) and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this direct final rule does not constitute a significant regulatory action under Executive Order 12866.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have preemptive effect. The final rule will

have retroactive effect to the enactment date of the statutory amendment. These changes will become effective December 28, 2020.

Executive Order 13132

This rule does not have federalism implications as defined in Executive Order 13132. The direct final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. Therefore, SBA determined that this direct final rule has no federalism implications warranting preparation of a Federalism Assessment.

Executive Order 13175

In accordance with Executive Order 13175, SBA has determined this rulemaking does not include policies that have Tribal implications.

Executive Order 13563

Executive Order 13563, Improving Regulation and Regulatory Review (January 18, 2011), requires agencies to adopt regulations through a process that involves public participation, and to the extent feasible, base regulations on the open exchange of information and perspectives from affected stakeholders and the public as a whole. SBA has developed this rule in a manner consistent with these requirements. This direct final rule makes statutorily required changes.

Congressional Review Act, 5 U.S.C. 801–808

The Office of Management and Budget has determined that this is not a major rule under 5 U.S.C. 804(2).

Paperwork Reduction Act (44 U.S.C. Ch. 35)

SBA has determined that this direct final rule would not impose any new reporting or recordkeeping requirements.

Regulatory Flexibility Act (5 U.S.C. 601–612)

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, including small businesses. According to the RFA, when an agency issues a rule, the agency must prepare an analysis to determine whether the impact of the rule will have a significant economic impact on a substantial number of small entities. However, the RFA allows an agency to certify a rule in lieu of preparing an analysis if the rulemaking is not expected to have a significant impact on a substantial number of small entities.

This rule only makes conforming amendments to the regulations due to recent legislation on the Microloan Program and does not implement new agency policies. The amendment will affect small entities; however, SBA has determined that the amendment will not have a significant economic impact on a substantial number of such entities.

D. Justification for Direct Final Rule—Administrative Procedure Act

In general, SBA publishes a rule for public comment before issuing a final rule in accordance with the Administrative Procedure Act. 5 U.S.C. 553. The Administrative Procedure Act provides an exception to this standard rulemaking process, however, where an agency finds good cause to adopt a rule without prior public participation. 5 U.S.C. 553(b)(3)(B). The good cause requirement is satisfied when prior public participation is impracticable, unnecessary, or contrary to the public interest.

SBA is publishing this rule as a direct final rule because public participation is unnecessary. SBA believes that this rule is routine and non-controversial since it merely implements changes required by statute, and SBA anticipates no significant adverse comments to this rulemaking. This rule will be effective on the date shown in the **DATES** section unless SBA receives significant adverse comment on or before the deadline for comments. Significant adverse comments are comments that provide strong justifications why the rule should not be adopted or for changing the rule. SBA does not expect to receive any significant adverse comments because it is adopting statutory changes.

If SBA receives any significant adverse comments, it will publish a document in the **Federal Register** withdrawing this rule before the effective date. If SBA receives no significant adverse comments, the rule will be effective 45 days after publication without further notice.

List of Subjects in 13 CFR Part 120

Definitions, Economically distressed area, Grant, Intermediary, Microloan, Rural area, Terms and conditions.

For reasons set forth in the preamble, the SBA amends 13 CFR part 120 as follows:

PART 120—MICROLOAN PROGRAM

■ 1. The authority citation for 13 CFR part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), (b)(7), (b)(14), (h), and note, 636(a), (h) and (m), and note, 636m, 650, 657t, and note, 657u, and note, 687(f), 696(3), and (7), and note, and 697, 697a and e, and note; Pub. L. 116–260, 134 Stat. 1182.

Subpart G—Microloan Program

■ 2. Revise § 120.701 to read as follows:

§ 120.701 Definitions.

Deposit account is a demand, time, savings, passbook, or similar account maintained with an insured depository institution (not including an account evidenced by a Certificate of Deposit).

Economically Distressed Area is a county or equivalent division of local government of a State in which the small business concern is located, in which, according to the most recent data available from the Bureau of the Census, Department of Commerce, not less than 40 percent of residents have an annual income that is at or below the poverty level.

Grant is a Federal award of money, or property in lieu of money (including cooperative agreements) to an eligible grantee that must account for its use. The term does not include the provision of technical assistance, revenue sharing, loans, loan guarantees, interest subsidies, insurance, direct appropriations, or any fellowship or other lump sum award.

Insured depository institution means any federally insured bank, savings association, or credit union.

Intermediary is an entity participating in the Microloan Program which makes and services Microloans to eligible small businesses and which provides marketing, management, and technical assistance to its borrowers. It may be:

(1) A private, nonprofit community development corporation or other entity;

(2) A consortium of private, nonprofit community development corporations or other entities;

(3) A quasi-governmental economic development entity, other than a state, county, municipal government or any agency thereof; or

(4) An agency of or a nonprofit entity established by a Native American Tribal Government.

Microloan is a short-term, fixed interest rate loan of not more than $50,000 made by an Intermediary to an eligible small business.

Non-Federal sources are sources of funds other than the Federal Government and may include indirect costs or in-kind contributions paid for under non-Federal programs. Community Block Development Grants are considered non-Federal sources.

Rural Area is any political subdivision or unincorporated area:

(1) In a nonmetropolitan county (as defined by the Secretary of Agriculture) or its equivalent thereof; or

(2) In a metropolitan county or its equivalent that has a resident population of less than 20,000 if the Small Business Administration has determined such political subdivision or area to be rural.

Specialized Intermediary is an Intermediary which maintains a portfolio of Microloans averaging $10,000 or less.

■ 3. Amend § 120.706 by revising paragraph (a) to read as follows:

§ 120.706 What are the terms and conditions of an SBA loan to an Intermediary?

(a) *Loan amount.* An Intermediary may not borrow more than $750,000 in the first year of participation in the program, or more than $3,000,000 in any subsequent year. An Intermediary's obligation to SBA may not exceed an aggregate of $7 million, subject to statutory limitations on the total amount of funds available per state.

* * * * *

■ 4. Amend § 120.712 by revising paragraphs (a) and (c) to read as follows:

§ 120.712 How does an Intermediary get a grant to assist Microloan borrowers?

(a) *General.* (1) Except as provided in (a)(2) of this section, an Intermediary is eligible to receive a base grant of not more than 25 percent of the outstanding balance of all SBA loans to the Intermediary.

(2) In fiscal years in which the amount appropriated for grants is sufficient to provide all Intermediaries with a base grant equal to 25 percent or more of their total outstanding SBA loan balances, then the amount of base grants to eligible Intermediaries will be equal to at least 25 percent of the outstanding balance of all SBA loans to the Intermediary and not more than 30 percent of such balance.

(3) The Intermediary must contribute, solely from non-Federal sources, an amount equal to 25 percent of the grant. Contributions may be made in cash or in kind.

* * * * *

(c) *Intermediaries eligible to receive additional bonus grant monies.* An Intermediary may receive an additional SBA grant equal to five percent of the outstanding balance of all loans received from SBA (with no obligation to contribute additional matching funds) if the Intermediary:

(1) Is a Specialized Intermediary;

(2) Provides not less than 25 percent of its loans to small business concerns located in or owned by one or more residents of an Economically Distressed Area; or

(3) Maintains a portfolio of Microloans of which at least 25 percent is serving Rural Areas.

* * * * *

Isabella C. Guzman,

Administrator.

[FR Doc. 2024–09520 Filed 5–1–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1817; Project Identifier MCAI–2023–00664–T; Amendment 39–22732; AD 2024–07–11]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This AD was prompted by a design review that identified the fixed emergency locator transmitter (ELT) lithium batteries would not be sufficiently cooled by the outside air in the event of a thermal runaway event. This AD requires replacing the ELT with a new ELT with redesigned batteries, as specified in a Transport Canada AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 6, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 6, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1817; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For material that is identified in this final rule, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1817.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The NPRM published in the **Federal Register** on September 6, 2023 (88 FR 60899). The NPRM was prompted by AD CF–2023–31, dated May 8, 2023 (Transport Canada AD CF–2023–31) (also referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. The MCAI states a design review identified that the fixed ELT lithium batteries would not be sufficiently cooled by the outside air in the event of a thermal runaway event. As a result, a thermal runaway could lead to an uncontrolled fire of the fixed ELT, which may compromise the structural integrity of the aircraft structure in the area where the fixed ELT is installed.

The FAA is issuing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1817.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association,

International (ALPA) who supported the NPRM without change.

The FAA received additional comments from Delta Air Lines (Delta). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Add Exception To Clarify Acceptable Compliance Methods

Delta requested that the FAA add an exception to clarify the acceptable compliance methods stated in Transport Canada AD CF–2023–31. Delta noted that Transport Canada AD CF–2023–31 states a compliance time of 48 months from the effective date of the AD, unless already accomplished and also states credit is provided if Airbus Canada Service Bulletin BD500–256006, Issue 001, dated March 15, 2021, or Issue 002, dated November 24, 2021, is done before the effective date of the AD. Delta states these statements are contradictory and does not provide credit for later revisions of the service bulletin (*i.e.,* Issues 003, 004, and 005). Delta requested that an exception paragraph be added to paragraph (h) of the proposed AD to specify that credit is given if actions are done before the effective date of the AD in accordance with Issues 001 through 005 of the service bulletin.

The FAA disagrees with the request to add an exception to this AD. The two statements are not contradictory. Paragraph (f) of this AD states to accomplish the required actions within the compliance times specified, ''unless already done.'' Therefore, if operators have accomplished the actions required for compliance with this AD before the effective date of this AD, no further action is necessary. Adding an exception to Transport Canada AD CF–2023–31 to provide credit for Issue 003, 004, and 005 of Airbus Canada Service Bulletin BD500–256006 is not necessary. Issue 003, 004, and 005 of Airbus Canada Service Bulletin BD500–256006 (and later approved revisions) are always acceptable methods of compliance for accomplishing the actions of this AD, whether done before or after the effective date of the AD. The FAA has not changed this AD in this regard.

Request for Exception To Correct Discrepancies in the Service Bulletin

Delta requested that the FAA add an exception in paragraph (h) of the proposed AD to correct for the following discrepancies in all issues 01 through 05 of Airbus Canada Service Bulletin BD500–256006.

1. Step 3.2.2 in Airbus Canada Service Bulletin BD500–256006 Issue 001, 002, and 003 states to keep the washers, and in Airbus Canada Service Bulletin BD500–256006 Issue 004 and 005 does not mention whether to keep or discard the washers. Delta stated that new washers are provided in the servicing kit.

2. Step 3.4.3 refers to bracket (4) in figure 4 instead of the correct bracket (8).

3. Step 3.4.4 refers to bracket (8) in figure 4 instead of the correct bracket (4).

4. Step 3.4.6 states to ''Do a countersink in the hole of the support (4) for the rivet (6).'' The support references the wrong item number, which should be support (3).

5. Step 3.5.3 states to ''torque the screw (7) (refer to AMP BD500–A–J20–31–00–00AAA–711A–A).'' Both, Step 3.5.3, and the AMP (Approved Maintenance Publications) reference do not include a torque value.

6. Step 1.ii.11. of Appendix 2 states to ''install the wire harness ID–TAG CPATE1033–001 over the EXPANDO on the marked location.'' Delta discovered that since the wire harness ID tag labeled CPATE1033–001 is a shrink wrap ID tag, it is not possible to remove as originally instructed in Steps 1.ii.7. and 8. of Appendix 2 and re-install over the EXPANDO (wire bundle protection sleeve). Delta requested that the proposed AD specify that it is acceptable to leave the ID tag access, where it is still visible under the EXPANDO.

The FAA agrees with the commenter's request, and confirmed with the manufacturer that the service information is incorrect. The manufacturer is considering addressing any errors in a future revision of Airbus Canada Service Bulletin BD500–256006. The FAA has added paragraphs (h)(2) through (7) to this AD to provide the requested clarification.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

Transport Canada AD CF–2023–31 specifies procedures for replacing the fixed ELT with an ELT with improved batteries that do not rely on cooling from the outside. The replacement includes modifying two electrical harnesses and installing a new ELT support assembly, ELT, and aircraft identification module (AIM). This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 71 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
19 work-hours × $85 per hour = $1,615	$12,804	$14,419	$1,023,749

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more

detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–07–11 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–22732; Docket No. FAA–2023–1817; Project Identifier MCAI–2023–00664–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 6, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–31, dated May 8, 2023 (Transport Canada AD CF–2023–31).

(d) Subject

Air Transport Association (ATA) of America Code: 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a design review that identified the fixed emergency locator transmitter (ELT) lithium batteries would not be sufficiently cooled by the outside air in the event of a thermal runaway event. The FAA is issuing this AD to address a thermal runaway that could lead to an uncontrolled fire of the fixed ELT. The unsafe condition, if not addressed, may compromise the structural integrity of the aircraft structure in the area where the fixed ELT is installed.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–31.

(h) Exceptions to Transport Canada AD CF–2023–31

(1) Where Transport Canada AD CF–2023–31 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Step 3.2.2 of the service information referenced in AD CF–2023–31 specifies to either to keep the washers or does not specify whether to keep or discard the washers, this AD requires the washers to be discarded.

(3) Where Step 3.4.3 of the service information referenced in AD CF–2023–31 specifies ''Backdrill three holes from the bracket (4) to a diameter of 0.160 to 0.164 in. (4.06 to 4.17 mm) in the support (3).'', for this AD, replace that text with ''Backdrill three holes from the bracket (8) to a diameter of 0.160 to 0.164 in. (4.06 to 4.17 mm) in the support (3).''

(4) Where Step 3.4.4 of the service information referenced in AD CF–2023–31 specifies ''Backdrill three holes from the bracket (8) to a diameter of 0.160 to 0.164 in. (4.06 to 4.17 mm) in the support (3).'', for this AD, replace that text with ''Backdrill three holes from the bracket (4) to a diameter of 0.160 to 0.164 in. (4.06 to 4.17 mm) in the support (3).''

(5) Where Step 3.4.6 of the service information referenced in AD CF–2023–31 specifies ''Do a countersink in the hole of the support (4) for the rivet (6)'', for this AD replace that text with ''Do a countersink in the hole of the support (3) for the rivet (6).''

(6) Where Step 3.5.3 of the service information referenced in AD CF–2023–31 specifies to torque the screw, this AD does not require that action.

(7) Where Steps 1.ii.7., 8. and 11. of Appendix 2 of the service information referenced in AD CF–2023–31 specifies to mark, remove, and re-install the wire harness ID tag CPATE1033–001, this AD does not require those actions.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Airbus Canada Limited Partnership's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Transport Canada AD CF–2023–31, dated May 8, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–31, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on April 4, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09352 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2402; Project Identifier MCAI–2023–00370–T; Amendment 39–22731; AD 2024–07–10]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes. This AD was prompted by a report indicating that a new filter plate connector for the nose wheel steering (NWS) system electronic control module (ECM) does not meet certain certification requirements. This AD requires replacing all affected ECMs. This AD also prohibits the installation of affected parts under certain conditions. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 6, 2024.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 6, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–2402; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For service information identified in this final rule, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–2402.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model CL–600–2B16 (601–3A, 601–3R, and 604 Variants) airplanes. The NPRM published in the **Federal Register** on December 28, 2023 (88 FR 89633). The NPRM was prompted by AD CF–2023–14R1, dated May 15, 2023 (Transport Canada AD CF–2023–14R1) (referred to after this as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. The MCAI states that the manufacturer of the NWS system ECM, part number (P/N) 601–86100–27, introduced a new filter plate connector that does not meet the certification requirements related to the susceptibility of electronic components to high intensity radiated field. This non-compliant filter plate connector, if not replaced, could result in a malfunction of the NWS system causing potential un-commanded steering or lateral excursion from the runway.

In the NPRM, the FAA proposed to require replacing all affected non-compliant ECMs. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–2402.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from two commenters, Bombardier and NetJets. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request to Provide a Figure Title

Both Bombardier and NetJets requested that a title be provided for the figure referenced in paragraph (g) of the NPRM because the title is missing.

The FAA agrees. The title ''Figure 1 to the introductory text of paragraph (g)—Applicable Bombardier Service Bulletins'' has been added to the referenced figure.

Request To Change the Applicability

Bombardier also requested that the Applicability of the proposed AD be changed. Bombardier noted that Model 601–3A and 601–3R variants are not impacted by this issue and should not be subject to this AD.

The FAA agrees. The Applicability of this AD has been changed accordingly.

Request for Clarification of Service Information Effectivity

NetJets noted that Bombardier Service Bulletin 650–32–006 is effective only for serial numbers 6050 through 6171. NetJets requested that the proposed AD be revised to provide direction for airplane serial numbers outside that range.

The FAA does not agree to revise this AD but will clarify. Bombardier has confirmed that all instructions in Service Bulletin 650–32–006 can be accomplished on serial numbers 6172 and subsequent. Because the affected ECMs are rotable parts, the FAA has determined that these parts could later be installed on airplanes that were initially delivered with acceptable ECMs, thereby subjecting those airplanes to the unsafe condition. The FAA has not changed this AD as a result of this comment.

Conclusion

This product has been approved by the aviation authority of another

country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following Bombardier service information.

- Service Bulletin 604–32–032, dated October 18, 2021.
- Service Bulletin 605–32–009, dated October 18, 2021.
- Service Bulletin 650–32–006, dated October 18, 2021.

This service information specifies procedures for removing and replacing all affected non-compliant ECMs, P/N 601–86100–27. These documents are distinct since they apply to different airplane configurations. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 164 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
6 work-hours × $85 per hour = $510	$75,972	$76,482	$12,543,048

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–07–10 Bombardier, Inc.: Amendment 39–22731; Docket No. FAA–2023–2402; Project Identifier MCAI–2023–00370–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 6, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model CL–600–2B16 (604 Variant) airplanes, certificated in any category, with serial numbers 5301 through 5665 inclusive, 5701 through 5990 inclusive, and 6050 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

(e) Unsafe Condition

This AD was prompted by a report indicating that a new filter plate connector for the nose wheel steering (NWS) system electronic control module (ECM) does not meet certain certification requirements. The FAA is issuing this AD to address this non-compliant filter plate connector, which, if not replaced, could result in a malfunction of the NWS system causing potential uncommanded steering or lateral excursion from the runway.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Verification of Airplane Technical Records

Within 24 months after the effective date of this AD: Inspect the serial number of the ECM, part number (P/N) 601–86100–27, in accordance with Section 2.B. Part A of the Accomplishment Instructions of the applicable service information listed in figure (1) to the introductory text of paragraph (g) of this AD to determine if the serial number of the ECM, P/N 601–86100–27, is listed in Table 1 of Section 1.A. of the applicable service information listed in figure (1) to the introductory text of paragraph (g) of this AD. A review of maintenance records is also acceptable if the serial number of the ECM can be conclusively determined from that review.

FIGURE 1 TO THE INTRODUCTORY TEXT OF PARAGRAPH (g)—APPLICABLE BOMBARDIER SERVICE BULLETINS

Model	Serial Nos.	Applicable bombardier service bulletin
CL–600–2B16	6050 and subsequent	650–32–006, dated October 18, 2021.
CL–600–2B16	5701 through 5990	605–32–009, dated October 18, 2021.
CL–600–2B16	5301 through 5665	604–32–032, dated October 18, 2021.

(1) If the serial number of the ECM is listed in Table 1 of Section 1.A. of the applicable service information or is not reidentified on the nameplate as SB–1, then the actions of paragraph (h) of this AD are required.

(2) If the serial number of the ECM is not listed in Table 1 of Section 1.A. of the applicable service information or is reidentified on the nameplate as SB–1, then the actions of paragraph (h) of this AD are not required.

(h) Replacement

For airplanes identified in paragraph (g)(1) of this AD: Do the actions specified in paragraphs (h)(1) and (2) of this AD.

(1) Within 24 months after the effective date of this AD: Replace the ECM, P/N 601–86100–27, identified in paragraph (g)(1) of this AD, in accordance with Section 2.C. Part B of the Accomplishment Instructions of the applicable service information listed in figure 1 to the introductory text of paragraph (g) of this AD.

(2) Prior to return to service, complete the operational test of the NWS system in accordance with Section 2.D. of the Accomplishment Instructions of the applicable service information listed in figure 1 to the introductory text of paragraph (g) of this AD.

(i) Parts Installation Limitation

As of the effective date of this AD, it is prohibited to install ECM, P/N 601–86100–27, as a replacement part, if the serial number is listed in Table 1 of Section 1.A. of the applicable service information listed in figure 1 to the introductory text of paragraph (g) of this AD, unless the ECM has been reidentified with SB–1 on the name plate.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager, International Validation Branch, mail it to the address identified in paragraph (k)(2) of this AD or email to: *9-avs-nyaco-cos@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Additional Information

(1) Refer to Transport Canada AD CF–2023–14R1, dated May 15, 2023, for related information. This Transport Canada AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–2402.

(2) For more information about this AD, contact Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 604–32–032, dated October 18, 2021.

(ii) Bombardier Service Bulletin 605–32–009, dated October 18, 2021.

(iii) Bombardier Service Bulletin 650–32–006, dated October 18, 2021.

(3) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website bombardier.com.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on April 2, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09351 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0029; Project Identifier MCAI–2023–01182–T; Amendment 39–22741; AD 2024–08–08]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–20–08, which applied to certain Airbus SAS Model A318, A319, A320, A321, A330–200, A330–200 Freighter, A330–300, A330–800, A330–900, A340–200, A340–300, A340–500, A340–600, and A380–800 series airplanes. AD 2021–20–08 required replacing certain nickel-cadmium (Ni-Cd) batteries with serviceable Ni-Cd batteries. This AD was prompted by a report that repetitive disconnection and reconnection of certain Ni-Cd batteries during airplane parking or storage could lead to a reduction in capacity of those batteries. This AD adds airplanes to the applicability and requires replacement of certain affected parts with serviceable parts as a precondition for return to service of airplanes from storage or parking, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 6, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 6, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0029; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for

Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2024–0029.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–20–08, Amendment 39–21746 (86 FR 57025, October 14, 2021) (AD 2021–20–08). AD 2021–20–08 applied to certain Airbus SAS Model A318, A319, A320, A321, A330–200, A330–200 Freighter, A330–300, A330–800, A330–900, A340–200, A340–300, A340–500, A340–600, and A380–800 series airplanes. AD 2021–20–08 required replacing certain Ni-Cd batteries with serviceable Ni-Cd batteries or maintaining the electrical storage capacity of those Ni-Cd batteries during airplane storage or parking. The FAA issued AD 2021–20–08 to address reduced capacity of certain Ni-Cd batteries, which could lead to reduced battery endurance performance and possibly result in failure to supply the minimum essential electrical power during abnormal or emergency conditions.

The NPRM published in the **Federal Register** on January 22, 2024 (89 FR 3897). The NPRM was prompted by AD 2023–0196, dated November 10, 2023 (EASA AD 2023–0196) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that it was determined that the on-wing preservation procedures originally provided for these airplanes did not ensure the expected preservation of the battery capacity.

In the NPRM, the FAA proposed to require replacement of certain affected parts with serviceable parts as a precondition for return to service of airplanes from storage or parking, as specified in EASA AD 2023–0196. The FAA is issuing this AD to address reduced capacity of certain Ni-Cd batteries. The unsafe condition, if not addressed, could lead to reduced battery endurance and possibly result in failure to supply the minimum essential electrical power during abnormal or emergency conditions.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0029.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International (ALPA) and an individual. Both commenters supported the NPRM without change.

The FAA received additional comments from American Airlines (AA), Delta Air Lines (DAL), United Airlines (UA), and two individuals. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Extend Compliance Time

DAL requested a 90-day transition period between AD 2021–20–08 and the new proposed AD requirements. DAL stated that compliance requirements and instructions are currently set to comply with AD 2021–20–08, and these requirements and instructions cannot be instantly transitioned the day the new AD becomes effective. As an example, DAL stated revising the Airbus A350 aircraft maintenance manual (AMM) can take 60 days due to complexity of the process. DAL explained that AD requirements that must be complied with as of the AD effective date can be set up and complied with if starting from zero AD mandated instructions, but when transitioning from one set of AD mandated instructions to a significantly different set of AD mandated instructions, a time of transition must be allowed for in the new AD.

The FAA partially agrees. The FAA concurs the requirement to replace affected batteries results in a new set of AD mandated instructions, but the FAA does not concur with a 90-day transition period (grace period). However, the FAA has determined that a 30-day grace period is appropriate and will not adversely affect safety. The FAA has added paragraph (h)(3) to this AD accordingly.

Request for Clarification of Terms

AAL requested clarification of ''parking and storage'' as intended by the proposed AD. The commenter asked whether ''parking and storage'' included extended heavy maintenance checks, such as an S-check that is abnormally extended beyond the 6-month time-limit due to inspection findings or material sourcing issues, or extended downtime for aircraft repair or modification such as a large repair for aircraft tug collision damage or a large-scale interior modification.

The FAA agrees to clarify. It is the responsibility of the operator to apply the relevant instructions provided in the AMM related to extended heavy maintenance checks or downtime for aircraft repair or modification. A dedicated preservation regime shall be defined in line with the maintenance activity requirements (for example, the need to keep batteries connected), based upon the applicable AMM parking and storage procedures. If a battery meets the definition of a ''serviceable part'' as specified in EASA AD 2023–0196, then the requirement to replace after ''parking and storage'' does not apply because it is not an affected part. However, if the battery meets the definition of an ''affected part'' as specified in EASA AD 2023–0196, the requirement to replace after ''parking and storage'' does apply.

Request To Remove Erroneous References

DAL and UA requested removal of any reference to parts manufacturer approval (PMA) batteries in the **SUMMARY** and Background of the NPRM. Delta also requested removal of the term ''PMA'' from the ''Related Service Information under 1 CFR part 51'' section of the NPRM. The commenters stated that the references are incorrect because those batteries are not referenced in the related EASA AD.

The FAA agrees. The **SUMMARY** and Background of the NPRM, as well as the ''Related Service Information Under 1 CFR part 51'' paragraph, incorrectly referred to PMA parts in describing the requirements of AD 2021–20–08 and the MCAI, which specify to replace certain Ni-Cd batteries. The FAA has removed the incorrect references to PMA parts from this AD.

Request To Withdraw the Proposed AD

A commenter asked what data there is to support the need for early replacement of the affected batteries. The FAA infers that the commenter is requesting withdrawal of the proposed AD.

The FAA does not agree with the inferred request to withdraw this AD. The FAA has obtained information to indicate that mandatory action is necessary to maintain the continued operational safety of these airplanes. This AD has not been changed regarding this inferred request.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0196 specifies procedures for procedures for replacing certain Ni-Cd batteries with serviceable Ni-Cd batteries. EASA AD 2023–0196 adds Model A300 series airplanes; Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); Model A310 series airplanes; and Model A350–941 and –1041 airplanes to the applicability. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 1,814 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
New actions	5 work-hours × $85 per hour = $425	$0	$425	$770,950

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2021–20–08, Amendment 39–21746 (86 FR 57025, October 14, 2021); and

■ b. Adding the following new AD:

2024–08–08 Airbus SAS: Amendment 39–22741; Docket No. FAA–2024–0029; Project Identifier MCAI–2023–01182–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 6, 2024.

(b) Affected ADs

This AD replaces AD 2021–20–08, Amendment 39–21746 (86 FR 57025, October 14, 2021) (AD 2021–20–08).

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (14) of this AD, certificated in any category.

(1) Model A300 B4–2C, B4–103, and B4–203 airplanes.

(2) Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes.

(3) Model A300 B4–605R and B4–622R airplanes.

(4) Model A300 C4–605R variant F airplanes.

(5) Model A300 F4–605R and F4–622R airplanes.

(6) Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(7) Model A318–111, –112, –121, and –122 airplanes.

(8) Model A319–111, –112, –113, –114, –115, –131, –132, –133, –151N, –153N, and –171N airplanes.

(9) Model A320–211, –212, –214, –216, –231, –232, –233, –251N, –252N, –253N, –271N, –272N, and –273N airplanes.

(10) Model A321–111, –112, –131, –211, –212, –213, –231, –232, –251N, –251NX, –252N, –252NX, –253N, –253NX, –271N, –271NX, –272N, and –272NX airplanes.

(11) Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, –343, –841, and –941 airplanes.

(12) Model A340–211, –212, –213, –311, –312, –313, –541, and –642 airplanes.

(13) Model A350–941 and A350–1041 airplanes.

(14) Model A380–841, –842, and –861 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by a report that repetitive disconnection and reconnection of certain nickel-cadmium (Ni-Cd) batteries during airplane parking or storage could lead to a reduction in capacity of those batteries. The FAA is issuing this AD to address reduced capacity of certain Ni-Cd batteries. The unsafe condition, if not addressed, could lead to reduced battery endurance and possibly result in failure to supply the minimum essential electrical power during abnormal or emergency conditions.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0196, dated November 10, 2023 (EASA AD 2023–0196).

(h) Exceptions to EASA AD 2023–0196

(1) Where EASA AD 2023–0196 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0196.

(3) The compliance for the replacement specified in paragraph (1) of EASA 2023–0196 is at the time specified in paragraph (1) of EASA AD 2023–0196, or within 30 days after the effective date of this AD, whichever occurs later.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information referenced in EASA AD 2023–0196 that contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0196, dated November 10, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0196, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 17, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09354 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1883; Project Identifier MCAI–2023–00804–T; Amendment 39–22734; AD 2024–08–01]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus SAS Model A350–941 airplanes. This AD was prompted by a report of cracks found on the trunnion arms of the inboard flap assemblies. This AD requires repetitive inspections for cracking of the trunnion arms of the inboard flap assembly, and applicable corrective actions, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. This AD also prohibits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 6, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 6, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1883; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this

material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–1883.

FOR FURTHER INFORMATION CONTACT: Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus SAS Model A350–941 airplanes. The NPRM published in the **Federal Register** on September 22, 2023 (88 FR 65328). The NPRM was prompted by AD 2023–0132, dated July 3, 2023 (EASA AD 2023–0132) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that cracks were found on the trunnion arms of the inboard flap assemblies that were made of forging aluminum 7037.

In the NPRM, the FAA proposed to require repetitive inspections for cracking of the trunnion arms of the inboard flap assembly, and applicable corrective actions, as specified in EASA AD 2023–0132. The NPRM also proposed to prohibit the installation of affected parts. The FAA is issuing this AD to address potential cracks of the trunnion arms. The unsafe condition, if not detected and corrected, could adversely affect the structural integrity of the trunnion arms.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1883.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Delta Airlines. The following presents the comment received on the NPRM and the FAA's response.

Request To Clarify Requirements

Delta Air Lines (Delta) requested that the proposed AD be revised to add a clear statement addressing the relation between the instructions in the service information specified in EASA AD 2023–0132 and paragraph (i)(2) of the proposed AD for any deviations to the instructions, including those that are Required for Compliance (RC). Delta pointed out that a note in Paragraph 3., Accomplishment Instructions, of Airbus Service Bulletin A350–57–P077, dated January 31, 2023, states to contact Airbus for any deviations to the instructions, including those that are RC. Delta added that paragraph (i)(2) of the proposed AD states that for any requirement in the AD to obtain instructions from a manufacturer, the instructions must be done using a method approved by the FAA, EASA, or Airbus' EASA Design Organization Approval (DOA). Delta provided several examples of cases where it has obtained approval from the manufacturer in accordance with the requirement defined in the proposed AD—a method that is DOA approved—and wondered if those types of deviations from instructions found in RC steps that are obtained from the manufacturer may be implemented without further FAA approval. Based on the language in the service information and paragraph (i)(2) of the proposed AD, Delta explained that it interprets this to mean that approval for any deviations from the service information—including RC steps—with a DOA approval may be used without further FAA approval.

The FAA disagrees with revising the regulatory text of this AD. However, the following explanation is provided for clarification of the RC process. Any deviation to any and all RC actions identified in required service information as ''in accordance with'' a specific method requires approval of an FAA alternative method of compliance (AMOC). The ''contact the manufacturer'' language in paragraph (i)(2) of this AD applies to RC actions within the service information that specify, for example, to ''contact the manufacturer [*e.g.,* Airbus] for repair instructions and do the repair.''

If the accomplishment step in the service information is labeled RC and has substeps or tasks with no paragraph designation under the labeled RC step, then all of the substeps or tasks must also be completed. In addition, if an accomplishment step in the service information is marked RC and states to do the work ''in accordance with'' a figure, drawing, or illustration, then all of the information in the figure, drawing, or illustration is mandatory. If a step is marked RC and a procedure or document must be followed to accomplish a task in a service bulletin, the appropriate terminology to cite the procedure or document is ''in accordance with.'' However, if a step is marked RC and a procedure or document may be followed to accomplish an action (*e.g.,* the design approval holder's procedure or document may be used, but an FAA-accepted procedure could also be used), the appropriate terminology to use to cite the procedure or document is ''refer to . . . as an accepted procedure.''

Additional Changes Made to This AD

Since the FAA issued the NPRM, EASA revised EASA AD 2023–0132 and issued EASA AD 2023–0132R1, dated March 20, 2024, which adds an optional terminating action for the repetitive inspections.

The FAA has revised paragraph (g) of this AD to also refer to EASA AD 2023–0132R1, dated March 20, 2024, as an appropriate source of service information for accomplishing the required actions.

The FAA has revised paragraph (c) of this AD to refer to EASA AD 2023–0132R1, dated March 20, 2024, for the affected airplanes, which are the same between EASA AD revisions.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0132 specifies procedures for repetitive ultrasonic inspections for cracking of the trunnion arms of the inboard flap assemblies, and corrective actions, as applicable. Corrective actions include obtaining and following repair instructions if any cracking is found. EASA AD 2023–0132 also prohibits the installation of affected parts.

EASA AD 2023–0132R1, dated March 20, 2024, specifies the same procedures as EASA AD 2023–0132 and provides on optional terminating action for the repetitive inspections, which consists of replacing the left-hand and right-hand inboard flap, as applicable, with a modified inboard flap.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 4 airplanes of U.S. registry. The

FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 17 work-hours × $85 per hour = $1,445	$10	Up to $1,455	Up to $5,820.

The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this AD.

ESTIMATED COSTS FOR OPTIONAL ACTIONS

Labor cost	Parts cost	Cost per product
Up to 122 work-hours × $85 per hour = $10,370	Up to $31,930	Up to $42,300.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–08–01 Airbus SAS: Amendment 39–22734; Docket No. FAA–2023–1883; Project Identifier MCAI–2023–00804–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 6, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2023–0132R1, dated March 20, 2024 (EASA AD 2023–0132R1).

(d) Subject

Air Transport Association (ATA) of America Code: 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report of cracks found on the trunnion arms of the inboard flap assemblies. The FAA is issuing this AD to address potential cracks of the trunnion arms. The unsafe condition, if not addressed, could adversely affect the structural integrity of the trunnion arms.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0132, dated July 3, 2023 (EASA AD 2023–0132) or EASA AD 2023–0132R1.

(h) Exceptions to EASA AD 2023–0132 and EASA AD 2023–0132R1

(1) Where EASA AD 2023–0132 refers to its effective date, or EASA AD 2023–0132R1 refers to July 17, 2023 (the effective date of EASA AD 2023–0132), this AD requires using the effective date of this AD.

(2) Where paragraph (2) of EASA AD 2023–0132 and EASA AD 2023–0132R1 specifies if ''any crack is detected, before next flight, contact Airbus for approved instructions and, within the compliance time(s) specified in those instructions, accomplish those instructions accordingly,'' this AD requires replacing that text with ''if any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0132 and EASA AD 2023–0132R1.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send

it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0132, dated July 3, 2023.

(ii) EASA AD 2023–0132R1, dated March 20, 2024.

Note 1 to paragraph (k)(2)(ii): EASA AD 2023–0132R1 can be accessed in the zipped file at the bottom of the web page for EASA AD 2023–0132. When EASA posts a revised AD on their website, they watermark the previous AD as ''Revised,'' alter the file name by adding ''_revised'' to the end, and move it into a zipped file attached at the bottom of the AD web page.

(3) For EASA AD 2023–0132 and EASA AD 2023–0132R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 12, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09353 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0222; Project Identifier MCAI–2023–01072–T; Amendment 39–22735; AD 2024–08–02]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain ATR—GIE Avions de Transport Régional Model ATR42 and ATR72 airplanes. This AD was prompted by a report of an electrical contactor that failed with contacts in the intermediate position, causing the airplane to lose power to multiple electrical systems. This AD requires repetitive operational tests of the affected part, and, depending on findings, accomplishment of applicable corrective action, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective June 6, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of June 6, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0222; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2024–0222.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to ATR—GIE Avions de Transport Régional Model ATR42–200, –300, –320, and –500; and ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes, except those on which ATR modification (mod) 05948 has been embodied in production. The NPRM published in the **Federal Register** on February 7, 2024 (89 FR 8361). The NPRM was prompted by AD 2023–0181, dated October 13, 2023 (EASA AD 2023–0181) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that one event of electrical failure has been reported on a pre-mod 05948 airplane, possibly caused by a functional item number (FIN) 1PA contactor failing with contacts in the intermediate position.

In the NPRM, the FAA proposed to require repetitive operational tests of the affected part, and, depending on findings, accomplishment of applicable corrective action, as specified in EASA AD 2023–0181. The FAA is issuing this AD to address an electrical failure. This condition, if not addressed, could lead to temporary loss of the direct current emergency electrical network and loss of control of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0222.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International, and an anonymous individual, both of whom supported the NPRM without change.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0181 specifies procedures for repetitive operational tests on the contactor 1PA, and, depending on findings, accomplishment of applicable corrective actions. Corrective actions include replacement of the contactor. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 49 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$4,165 per test.

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
2 work-hours × $85 per hour = $170	$1,625	$1,795

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–08–02 ATR—GIE Avions de Transport Régional: Amendment 39–22735; Docket No. FAA–2024–0222; Project Identifier MCAI–2023–01072–T.

(a) Effective Date

This airworthiness directive (AD) is effective June 6, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the ATR—GIE Avions de Transport Régional airplanes specified in paragraphs (c)(1) and (2) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2023–0181, dated October 13, 2023 (EASA AD 2023–0181).

(1) Model ATR42–200, –300, –320, and –500 airplanes.

(2) Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Unsafe Condition

This AD was prompted by a report of an electrical contactor that failed with contacts in the intermediate position, causing the airplane to lose power to multiple electrical systems. The FAA is issuing this AD to address an electrical failure. The unsafe condition, if not addressed, could result in temporary loss of the direct current emergency electrical network and loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0181.

(h) Exceptions to EASA AD 2023–0181

(1) Where EASA AD 2023–0181 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0181.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or ATR—GIE Avions de Transport Régional's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 206–231–3220; email: *shahram.daneshmandi@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0181, dated October 13, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0181, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations,* or email *fr.inspection@nara.gov.*

Issued on April 12, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–09355 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 5O, 8M, and 44A

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing three general licenses (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 8M, GL 5O, and GL 44A, each of which was previously made available on OFAC's website.

DATES: GL 8M was issued on November 16, 2023. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

On November 16, 2023, OFAC issued GL 8M to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations (VSR), 31 CFR part 591. GL 8M was made available on OFAC's website (*https://ofac.treasury.gov/*) when it was issued. GL 8M supersedes GL 8L, which was issued on May 23, 2023. GL 8M has an expiration date of May 16, 2024.

On April 15, 2024, OFAC issued GL 5O to authorize certain transactions otherwise prohibited by the VSR. GL 5O was made available on OFAC's website (*https://ofac.treasury.gov/*) when it was issued. GL 5O supersedes GL 5N, which was issued on January 16, 2024. GL 5O has an expiration date of August 13, 2024.

On April 17, 2024, OFAC issued GL 44A to authorize certain transactions otherwise prohibited by the VSR. GL 44A was made available on OFAC's website (*https://ofac.treasury.gov/*) when it was issued. GL 44A supersedes GL 44, which was issued on October 18, 2023. GL 44A has an expiration date of May 31, 2024.

The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 8M

Authorizing Transactions Involving Petróleos de Venezuela, S.A. (PdVSA) Necessary for the Limited Maintenance of Essential Operations in Venezuela or the Wind Down of Operations in Venezuela for Certain Entities

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to the limited maintenance of essential operations, contracts, or other agreements, that: (i) are for safety or the preservation of assets in Venezuela; (ii) involve PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest; and (iii) were in effect prior to July 26, 2019, are

authorized through 12:01 a.m. eastern daylight time, May 19, 2024, for the following entities and their subsidiaries (collectively, the ''Covered Entities''):

- Halliburton
- Schlumberger Limited
- Baker Hughes Holdings LLC
- Weatherford International, Public Limited Company

Note to paragraph (a): Transactions and activities necessary for safety or the preservation of assets in Venezuela that are authorized by paragraph (a) of this general license include: transactions and activities necessary to ensure the safety of personnel, or the integrity of operations and assets in Venezuela; participation in shareholder and board of directors meetings; making payments on third-party invoices for transactions and activities authorized by paragraph (a) of this general license, or incurred prior to April 21, 2020, provided such activity was authorized at the time it occurred; payment of local taxes and purchase of utility services in Venezuela; and payment of salaries for employees and contractors in Venezuela.

(b) Except as provided in paragraph (d) of this general license, all transactions and activities prohibited by E.O. 13850, as amended, or E.O. 13884, each as incorporated into the VSR, that are ordinarily incident and necessary to the wind down of operations, contracts, or other agreements in Venezuela involving PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, and that were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern daylight time, May 16, 2024, for the Covered Entities.

(c) Paragraph (a) of this general license does not authorize:

(1) The drilling, lifting, or processing of, purchase or sale of, or transport or shipping of any Venezuelan-origin petroleum or petroleum products;

(2) The provision or receipt of insurance or reinsurance with respect to the transactions and activities described in paragraph (c)(1) of this general license;

(3) The design, construction, installation, repair, or improvement of any wells or other facilities or infrastructure in Venezuela or the purchasing or provision of any goods or services, except as required for safety;

(4) Contracting for additional personnel or services, except as required for safety; or

(5) The payment of any dividend, including in kind, to PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest.

(d) This general license does not authorize:

(1) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(2) Any loans to, accrual of additional debt by, or subsidization of PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, including in kind, prohibited by E.O. 13808 of August 24, 2017, as amended by E.O. 13857, and incorporated into the VSR; or

(3) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked person other than the blocked persons identified in paragraphs (a) and (b) of this general license.

(e) Effective November 16, 2023, General License No. 8L, dated May 23, 2023, is replaced and superseded in its entirety by this General License No. 8M.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: November 16, 2023.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 5O

Authorizing Certain Transactions Related to the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond on or After August 13, 2024

(a) Except as provided in paragraph (b) of this general license, on or after August 13, 2024, all transactions related to, the provision of financing for, and other dealings in the Petróleos de Venezuela, S.A. 2020 8.5 Percent Bond that would be prohibited by subsection l(a)(iii) of Executive Order (E.O.) 13835 of May 21, 2018, as amended by E.O. 13857 of January 25, 2019, and incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized.

(b) This general license does not authorize any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V.

(c) Effective April 15, 2024, General License No. 5N, dated January 16, 2024, is replaced and superseded in its entirety by this General License No. 5O.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: April 15, 2024.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 44A

Authorizing the Wind Down of Transactions Related to Oil or Gas Sector Operations in Venezuela

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), including transactions involving Petróleos de Venezuela, S.A. (PdVSA) or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest (collectively, ''PdVSA Entities''), that are ordinarily incident and necessary to the wind down of any transaction related to oil or gas sector operations in Venezuela previously authorized by Venezuela General License 44 are authorized through 12:01 a.m. eastern daylight time May 31, 2024.

(b) This general license does not authorize:

(1) Any transactions involving any financial institution blocked pursuant to Executive Order (E.O.) 13850 other than Banco Central de Venezuela or Banco de Venezuela SA Banco Universal;

(2) The provision of goods or services to, or new investment in, an entity located in Venezuela that is owned or controlled by, or a joint venture with, an entity located in the Russian Federation;

(3) Any transactions related to new investment in oil or gas sector operations in Venezuela by a person located in the Russian Federation or any entity owned or controlled by a person located in the Russian Federation;

(4) Any transactions prohibited by subsections 1(a)(i)–(iii) or 1(b) of E.O. 13808, other than the payment of invoices for goods or services related to oil or gas sector operations in Venezuela, or delivery of oil or gas from Venezuela to creditors of the Government of Venezuela, including creditors of PdVSA Entities, for the purpose of debt repayment;

(5) Any transactions prohibited by E.O. 13827 or E.O. 13835; or

(6) The unblocking of any property blocked pursuant to the VSR.

(c) Effective April 17, 2024, General License No. 44, dated October 18, 2023, is replaced and superseded in its entirety by this General License No. 44A.

Note to General License No. 44A. Nothing in this general license relieves any person from compliance with the requirements of other Federal agencies, including the

Department of Commerce's Bureau of Industry and Security.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: April 17, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–09530 Filed 5–1–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2024–0319]

RIN 1625–AA08

Special Local Regulation; Bush River and Otter Point Creek; Between Perryman, MD and Edgewood, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for certain waters of the Bush River and Otter Point Creek, in Maryland. This action is necessary to provide for the safety of life on these navigable waters located at Edgewood, MD during a high-speed power boat race on May 11, 2024, and May 12, 2024. This regulation prohibits persons and vessels (other than those already at berth at the time the regulation takes effect) from being in the regulated area unless authorized by the Captain of the Port, Sector Maryland-National Capital Region (COTP), or a designated representative.

DATES: This rule is effective from 9 a.m. to 7 p.m. on May 11 and 12, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0168 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST2 Hollie Givens, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port, Sector Maryland-National Capital Region
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Kent Narrows Racing Association (KNRA) applied for a permit under 33 CFR 100.15 to conduct the Harford County Spring Nationals Inboard Hydroplane Race on May 11, 2024, and May 12, 2024, from 10 a.m. to 6 p.m. on both days. The high-speed power boat racing event consists of approximately 60 participating racing boats—including composite and wood hull inboard hydroplanes—12 to 28 feet in length. Following the approval of a permit, the COTP may issue special local regulations under 33 CFR 100.35, as the Coast Guard is doing in the form of this temporary final rule.

The Coast Guard is issuing this temporary rule under procedural authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable to provide notice, consider any comments received, and publish a final rule by May 11, 2024, when the rule must be in place to address the potential safety hazards associated with the high-speed power boat race.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. There are fewer than 30 days between now and May 11, making a 30-day delay in the effective date impracticable if the rule is to serve its purpose of addressing to the potential safety hazards associated with the high-speed power boat race.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The COTP has determined that potential hazards associated with the power boat races would be a safety concern for anyone intending to participate in this event and for vessels that operate within the specified waters of the Bush River and Otter Point Creek. The purpose of this rule is to protect event participants, non-participants, and transiting vessels before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a regulated area from 9 a.m. on May 11, 2024, through 7 p.m. on May 12, 2024. Although it will be in effect during that period, it will only be enforced from 9 a.m. to 7 p.m. on May 11, 2024, and from 9 a.m. to 7 p.m. on May 12, 2024. The regulated area will cover all navigable waters of the Bush River and Otter Point Creek, shoreline to shoreline, bounded to the north by a line drawn from the western shoreline of the Bush River at latitude 39°21′15″ N, longitude 076°14′39″ W and thence eastward to the eastern shoreline of the Bush River at latitude 39°27′03″ N, longitude 076°13′57″ W, and bounded to the south by the Amtrak Railroad Bridge, across the Bush River at mile 6.8, between Perryman, MD and Edgewood, MD. These boundaries are based on a detailed course map for the event which the Coast Guard received from the sponsor on March 7, 2023.

The COTP, and the Coast Guard Event Patrol Commander (or ''Event PATCOM,'' a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been so designated by the COTP) will have authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area will be required to immediately comply with the directions given by the COTP or Event PATCOM. If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both.

Except for Harford County Spring Nationals participants and vessels already at berth, a vessel or person will be required to get permission from the COTP or Event PATCOM before entering the regulated area. Vessel operators will be able to request permission to enter and transit through the regulated area by contacting the Event PATCOM on VHF–FM channel 16. Vessel traffic will be able to safely transit the regulated area once the Event PATCOM deems it safe to do so. A vessel within the regulated area must operate at a safe speed that minimizes wake. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols will be considered a spectator. Official Patrols are any vessel assigned or approved by the COTP with a commissioned, warrant, or petty officer onboard and displaying a Coast Guard ensign.

Official Patrols enforcing this regulated area can be contacted on VHF–FM channel 16 and channel 22A.

If permission is granted by the COTP or Event PATCOM, a person or vessel will be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels will be required to operate at a safe speed in a manner that minimizes wake while within the regulated area and that would not endanger event participants or any other craft. A spectator vessel must not loiter within the navigable channel while present within the regulated area. Only participant vessels and official patrol vessels will be allowed to enter the race area. The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event dates and times.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size and duration of the regulated area, which will impact a small, designated area of the Bush River for a total of 20 enforcement hours. Although this regulated area extends across a large portion of the waterway, the rule will allow vessels and persons to seek permission to enter the regulated area, and if able to do so safely, vessel traffic will be able to transit the regulated area as instructed by the Event PATCOM. Such vessels must operate at a safe speed that minimizes wake and not loiter within the navigable channel while present within the regulated area. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area.

B. Impact on Small Entities

In the spirit of 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves implementation of regulations within 33 CFR 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area for 20 total enforcement hours. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T599–0319 to read as follows:

§ 100.T995–0319 Special Local Regulation; Bush River and Otter Point Creek; Between Perryman, MD and Edgewood, MD.

(a) *Location.* All coordinates are based on datum NAD 1983.

(1) *Regulated area.* All navigable waters of Bush River and Otter Point Creek, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline of the Bush River at latitude 39°27′15″ N, longitude 076°14′39″ W and thence eastward to the eastern shoreline of the Bush River at latitude 39°27′03″ N, longitude 076°13′57″ W; and bounded to the south by the Amtrak Railroad Bridge, across the Bush River at mile 6.8, between Perryman, MD and Edgewood, MD. The following locations are within the regulated area: The regulations in this section apply to the following area:

(2) *Race Area.* The area is bounded by a line commencing at position latitude 39°26′39.48″ N, longitude 076°15′23.44″ W, to latitude 39°26′36.52″ N, longitude 076°15′13.33″ W, to latitude 39°26′36.94″ N, longitude 076°15′10.01″ W, to latitude 39°26′38.59″ N, longitude 076°15′07.41″ W, to latitude 39°26′41.03″ N, longitude 076°15′06.22″ W, to latitude 39°26′43.61″ N, longitude 076°15′06.76″ W, to latitude 39°26′45.63″ N, longitude 076°15′08.89″ W, to latitude 39°26′47.93″ N, longitude 076°15′16.76″ W, to latitude 39°26′50.24″ N, longitude 076°15′24.63″ W, to latitude 39°26′49.81″ N, longitude 076°15′27.95″ W, to latitude 39°26′48.16″ N, longitude 076°15′30.56″ W, to latitude 39°26′45.72″ N, longitude 076°15′31.75″ W, to latitude 39°26′43.15″ N, longitude 076°15′31.20″ W, to latitude 39°26′41.13″ N, longitude 076°15′29.07″ W thence back to the beginning point.

(3) *Buffer Zone.* The buffer zone surrounds the entire race area and is bounded by a line commencing at position latitude 39°26′39.60″ N, longitude 076°15′30.00″ W, to latitude 39°26′37.80″ N, longitude 076°15′24.00″ W, to latitude 39°26′34″ N, longitude 076°15′14.40″ W, to latitude 39°26′34.80″ N, longitude 076°15′09.00″ W, to latitude 39°26′37.20″ N, longitude 076°15′05.40″ W, to latitude 39°26′40.80″ N, longitude 076°15′03.60″ W, to latitude 39°26′44.40″ N, longitude 076°15′04.20″ W, to latitude 39°26′46.80″ N, longitude 076°15′07.20″ W, to latitude 39°26′49.80″ N, longitude 076°15′15.60″ W, to latitude 39°26′52.20″ N, longitude 076°15′25.20″ W, to latitude 39°26′51.60″ N, longitude 076°15′28.80″ W, to latitude 39°26′49.20″ N, longitude 076°15′32.40″ W, to latitude 39°26′45.60″ N, longitude 076°15′34.20″ W, to latitude 39°26′42.60″ N, longitude 076°615′33.60″ W thence back to the beginning point.

(4) *Spectator Area.* The spectator area is designated as all the waters immediately surrounding the buffer zone up to a distance of 500 feet immediately surrounding the buffer zone.

(b) *Definitions.* As used in this section—

Buffer Zone is a neutral area that surrounds the perimeter of the race area within the regulated area described by this section. The purpose of a buffer area is to minimize potential collision conflicts with marine event participants or high-speed power boats and nearby transiting vessels. This area provides separation between a race area and other vessels that are operating in the vicinity of the regulated area established by the special local regulations in this section.

Designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Maryland-National Capital Region (COTP) in the enforcement of the regulations in this section.

Event Patrol Commander or Event PATCOM means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been so designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official patrol means any vessel assigned or approved by Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participant means all persons and vessels registered with the event sponsor as a participant in the race.

Race area is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of a race area within the regulated area defined by this section.

Spectator means a person or vessel not registered with the event sponsor as a participant or assigned as official patrols.

(c) *Regulations.* (1) The COTP Maryland-National Capital Region or Event PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area described in paragraph (a)(1) of this section. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Maryland-National Capital Region or Event PATCOM may terminate the event, or a participant's operations at any time the COTP Maryland-National Capital Region or Event PATCOM believes it necessary to do so for the protection of life or property.

(2) Except for participants and vessels already at berth, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) A spectator must contact the Event PATCOM to request permission to either enter or pass through the regulated area. The Event PATCOM, and official patrol vessels enforcing this regulated area, can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). If permission is granted, the spectator must pass directly through the regulated area as instructed by Event PATCOM. A vessel within the regulated area must operate at safe speed that minimizes wake. A spectator vessel must not loiter within the navigable channel while within the regulated area.

(4) Only participant vessels and official patrol vessels are allowed to enter and remain within the race area.

(5) Only participant vessels and official patrol vessels are allowed to enter and transit directly through the buffer area in order to arrive at or depart from the race area.

(6) A person or vessel that desires to transit, moor, or anchor within the regulated area must obtain authorization from the COTP Maryland-National Capital Region or Event PATCOM. A person or vessel seeking such permission can contact the COTP Maryland-National Capital Region at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz) or the Event PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(7) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event dates and times.

(d) *Enforcement officials.* The Coast Guard may be assisted with marine event patrol and enforcement of the regulated area by other federal, state, and local agencies.

(e) *Enforcement period.* This section will be enforced from 9 a.m. to 7 p.m.

on May 11, 2024, and from 9 a.m. to 7 p.m. on May 12, 2024.

Dated: April 26, 2024.

David E. O'Connell,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2024–09548 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0316]

Special Local Regulation; Marine Events Within the Captain of the Port Miami

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Fort Lauderdale Air Show event from May 9–12, 2024, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Captain of the Port Miami identifies the regulated area for this event in Fort Lauderdale, FL. During the enforcement periods, no person or vessel may enter, transit through, anchor in, or remain within the regulated area unless authorized by the Coast Guard Patrol Commander or a designated representative.

DATES: The regulation in 33 CFR 100.702, will be enforced from 9 a.m. through 6 p.m., from May 9, 2024, through May 12, 2024, for the regulated area listed in item no. 3 of table 1 to § 100.702.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Robert Michael Olivas, Sector Miami Waterways Management Division, U.S. Coast Guard: telephone 305–535–4317, Email: *Robet.M.Olivas2@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulation in 33 CFR 100.702 for the Fort Lauderdale Air Show event regulated area identified in table 1 to § 100.702, item no. 3, from 9 a.m. through 6 p.m., each day from May 9, 2024, through May 12, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Marine Events within the Captain of the Port Miami § 100.702, table 1, item 3, specifies the location of the regulated area Fort Lauderdale Air Show event which encompasses portions of Atlantic Ocean and Fort Lauderdale Beach. Under the provisions of § 100.702(c), all persons and vessels are prohibited from entering the regulated area, except those persons and vessels participating in the event, unless they receive permission to do so from the Coast Guard Patrol Commander, or designated representative.

Under the provisions of § 100.702,(c) spectator vessels may safely transit outside the regulated area, but may not anchor, block, loiter in, impede the transit of festival participants or official patrol vessels or enter the regulated area without approval from the Coast Guard Patrol Commander or a designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notice of the regulated area via Local Notice to Mariners, Marine Safety Information Bulletins, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: April 26, 2024.

C.R. Cederholm,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2024–09535 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2024–0315]

Special Local Regulations: Marine Events Within the Captain of the Port Miami

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Miami Beach Air and Sea Show event from May 25 and 26, 2024, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Captain of the Port Miami identifies the regulated area for this event in Miami Beach, FL. During the enforcement periods, no person or vessel may enter, transit through, anchor in, or remain within the regulated area unless authorized by the Coast Guard Patrol Commander or a designated representative.

DATES: The regulations in 33 CFR 100.702 will be enforced from 9 a.m. through 7 p.m., on May 25 and 26, 2024, for the regulated are listed in Item No. 2 of Table 1 to § 100.702.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Mr. Robert M. Olivas, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305–535–4317, email at *Robert.M.Olivas2@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.702 for the Miami Beach Air and Sea Show event regulated area identified in Table 1 to § 100.702, Item No. 2, from 9 a.m. through 7 p.m. on May 25 and 26, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for Marine Events within the Captain of the Port Miami in Table 1 to § 100.702, Item No. 2, specifies the location of the regulated area for the Miami Beach Air and Sea Show which encompasses portions of Miami Beach. Under the provisions of § 100.702(c), all persons and vessels are prohibited from entering the regulated area, except those persons and vessels participating in the event, unless they receive permission to do so from the Coast Guard Patrol Commander, or designated representative.

Under the provisions of § 100.702(c), spectator vessels may safely transit outside the regulated area, but may not anchor, block, loiter in, impede the transit of festival participants or official patrol vessels or enter the regulated area without approval from the Coast Guard Patrol Commander or a designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notice of the regulated area via Local Notice to Mariners, Marine Safety Information Bulletins, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: April 26, 2024.

C.R. Cederholm,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2024–09534 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket Number USCG–2023–0277]

RIN 1625–AA00

Safety Zone; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is extending the effective period for the 63 temporary 500-meter safety zones around the construction of each facility during the development of the Vineyard Wind 1 Wind Farm project area within federal waters on the Outer Continental Shelf, approximately 12 nautical miles offshore of Martha's Vineyard, Massachusetts. This rule extends the effective period of the existing safety zones for an additional two years. The safety zones will now end on May 31, 2026. When enforced, only attending vessels and vessels with authorization are permitted to enter or remain in the safety zones.

DATES: This temporary interim rule is effective from June 1, 2024, through May 31, 2026. Comments and related material must be received by the Coast Guard on or before July 31, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0277 using the Federal eRulemaking Portal at *https://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0277 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Craig Lapiejko, Waterways Management, at Coast Guard First District, telephone 617–603–8592, email *craig.d.lapiejko@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
ESP Electrical Service Platform
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
NM Nautical Mile
§ Section
U.S.C. United States Code
WTG Wind Turbine Generator
VHF–FM Very High Frequency—Frequency Modulation
VW1WF Vineyard Wind 1 Wind Farm

II. Background, Purpose, and Legal Basis

On June 30, 2023, the Coast Guard published a temporary final rule (TFR) establishing 63 temporary 500-meter safety zones around the construction of 62 wind turbine generators (WTGs) and one electrical service platform (ESP) located in the Vineyard Wind 1 Wind Farm (VW1WF) project area within federal waters on the Outer Continental Shelf (OCS), specifically in the northern portion of Bureau of Ocean Energy Management Renewable Energy Lease Area OCS–A 0501, approximately 12 nautical miles (NM) offshore of Martha's Vineyard, Massachusetts and 12 NM offshore Nantucket, Massachusetts. (88 FR 42237).

The Coast Guard originally published a temporary rule to be effective, and enforceable, through May 31, 2024. We are now extending it to May 31, 2026, to provide more time for the completion of the installation of the WTG structures. This rule extends the effective period of the safety zones for two years until May 31, 2026.

The First Coast Guard District Commander has determined that extension of the 63 safety zones through rulemaking is warranted to ensure the safety of life, property, and the environment within a 500-meter radius of each of the 63 facilities during their construction.

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to extending the effective period for the safety zone because doing so would be impracticable and contrary to the public interest. The Coast Guard did not receive sufficient notice that the windfarm construction would not be completed until May 31, 2026, to allow time to publish an NPRM, reviewing public comment, and publishing a subsequent rule. Providing this prior public notice and opportunity to comment is contrary to the public's interest and impracticable because doing so could result in a lapse in the safety zone's enforceability, and safety concerns with vessels and persons transiting too close to the construction efforts. Immediate action is needed to protect persons and property from the potential dangers associated with the construction.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary interim rule effective less than 30 days after publication in the **Federal Register**. The current temporary final rule around the windfarm construction ends on May 31, 2024, but the construction will be ongoing after that date. Delaying the effective date of this temporary interim rule would be contrary to the public's interest and impracticable because action is needed starting June 1, 2024, to protect persons and vessels from the potential safety hazards associated with the ongoing windfarm construction.

We are soliciting comments on the extension of the enforcement period of this safety zone. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority provided in 14 U.S.C. 544, 43 U.S.C. 1333, and Department of Homeland Security (DHS) Delegation No. 00170.1, Revision No. 01.3. As an implementing regulation of this authority, 33 CFR part 147 permits the establishment of safety zones for non-mineral energy resource permanent or temporary structures located on the OCS for the purpose of protecting life and property on the facilities, appurtenances and attending vessels, and on the adjacent waters within the safety zone (see 33 CFR 147.10). Accordingly, a safety zone established under 33 CFR part 147 may also include provisions to restrict, prevent, or control certain activities, including access by vessels or persons to maintain safety of life, property, and the environment.

IV. Discussion of Comments, Changes, and the Rule

This rule extends the effective period of the 63 temporary 500-meter safety zones around the construction of 62 WTGs and one ESP on the OCS for two

additional years until May 31, 2026. When enforced, this rule will continue to prohibit unauthorized vessel or person to enter the safety zone without obtaining permission from the First Coast Guard District Commander or a designated representative. All other requirements in the temporary safety zone issued on June 30, 2023 (88 FR 42237) remain the same.

If the project is completed before May 31, 2026, enforcement of the safety zones will be suspended, and notice given via Local Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. A summary of our analyses based on these statutes and Executive Orders follows.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866 as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB).

Aligning with 33 CFR 147.15, the safety zones established will extend to a maximum distance of 500-meters around the OCS facility measured from its center point. Vessel traffic will be able to safely transit around the safety zones, which will impact a small, designated area in the Atlantic Ocean, without significant impediment to their overall voyage. These safety zones are necessary to provide for the safety of life, property, and the environment during the construction of each structure, in accordance with Coast Guard maritime safety missions and the First Coast Guard District Commander's finding.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received zero comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

This rule may affect owners or operators of vessels intending to transit or anchor in the VW1WF, some of which might be small entities. However, these safety zones will not have a significant economic impact on a substantial number of these entities because they are temporarily enforced, allow for deviation requests, and do not impact vessel transit significantly. Regarding the enforcement period, although these safety zones will continue to be in effect through May 31, 2026, vessels would only be prohibited from the regulated zone during periods of actual construction activity in correspondence to the period of enforcement. We expect the enforcement period at each location to last approximately 48 hours as construction progresses from one structure location to the next. Additionally, vessel traffic could pass safely around each safety zone using an alternate route. Use of an alternate route likely will cause minimal delay for the vessel in reaching their destination depending on other traffic in the area and vessel speed. Vessels will also be able to request deviation from this rule to transit through a safety zone. Such requests will be considered on a case by-case basis and may be authorized by the First Coast Guard District Commander or a designated representative. For these reasons, the Coast Guard expects any impact of this rulemaking establishing a temporary safety zone around these OCS facilities to be minimal and have no significant economic impact on small entities.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist all small entities in understanding this temporary final rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This temporary final rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this temporary final rule will not result in such an expenditure, we do discuss the potential effects of this temporary final rule elsewhere in this preamble.

F. Environment

We have analyzed this final rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one

of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of safety zones around an OCS facility to protect life, property, and the marine environment. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. If we determine that changes to the temporary interim rule are necessary, the Coast Guard will publish a temporary final rule or other appropriate document. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov*. To do so, go to *https://www.regulations.gov*, type USCG–2023–0277 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov*, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this temporary interim rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the temporary interim rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a subsequent document is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (waters).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 544; 43 U.S.C. 1333; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Revise and republish § 147.T01–0277 to read as follows:

§ 147.T01–0277 Safety Zones; Vineyard Wind 1 Wind Farm Project Area, Outer Continental Shelf, Lease OCS–A 0501, Offshore Massachusetts, Atlantic Ocean.

(a) *Description.* The area within 500-meters of the center point of the positions provided in the following table 1 to paragraph (a) is a safety zone:

TABLE 1 TO PARAGRAPH (a)

Name	Facility type	Latitude	Longitude
AL38	WTG	N 41.1370161	W −70.4638911
AM37	ESP	N 41.1200616	W −70.4851682
AM38	WTG	N 41.1203387	W −70.4635204
AM39	WTG	N 41.1206168	W −70.4414663
AN36	WTG	N 41.1030927	W −70.5072461
AN37	WTG	N 41.1033791	W −70.4851982
AN38	WTG	N 41.1036612	W −70.4631500
AN39	WTG	N 41.1039392	W −70.4411014
AP35	WTG	N 41.0861251	W −70.5289069
AP36	WTG	N 41.0864155	W −70.5068649
AP37	WTG	N 41.0867017	W −70.4848226
AP38	WTG	N 41.0869837	W −70.4627799
AP39	WTG	N 41.0872615	W −70.4407369
AP40	WTG	N 41.0875351	W −70.4186937
AP41	WTG	N 41.0878044	W −70.3966501
AQ34	WTG	N 41.0691535	W −70.5505566
AQ35	WTG	N 41.0694480	W −70.5285205
AQ36	WTG	N 41.0697382	W −70.5064840
AQ37	WTG	N 41.0700243	W −70.4844472
AQ38	WTG	N 41.0703061	W −70.4624101
AQ39	WTG	N 41.0705837	W −70.4403727
AQ40	WTG	N 41.0708571	W −70.4183350
AQ41	WTG	N 41.0711263	W −70.3962970
AQ42	WTG	N 41.0713913	W −70.3742587
AR33	WTG	N 41.0521781	W −70.5721951
AR34	WTG	N 41.0524766	W −70.5501649
AR35	WTG	N 41.0527709	W −70.5281343

TABLE 1 TO PARAGRAPH (a)—Continued

Name	Facility type	Latitude	Longitude
AR36	WTG	N 41.0530609	W −70.5061034
AR37	WTG	N 41.0533468	W −70.4840722
AR38	WTG	N 41.0536285	W −70.4620407
AR39	WTG	N 41.0539059	W −70.4400088
AR40	WTG	N 41.0541792	W −70.4179767
AR41	WTG	N 41.0544482	W −70.3959442
AR42	WTG	N 41.0547130	W −70.3739115
AS32	WTG	N 41.0351987	W −70.5938225
AS33	WTG	N 41.0355012	W −70.5717982
AS34	WTG	N 41.0357995	W −70.5497735
AS35	WTG	N 41.0360937	W −70.5277485
AS36	WTG	N 41.0363836	W −70.5057231
AS37	WTG	N 41.0366693	W −70.4836975
AS38	WTG	N 41.0369508	W −70.4616715
AS39	WTG	N 41.0372281	W −70.4396452
AS40	WTG	N 41.0375012	W −70.4176186
AS41	WTG	N 41.0377701	W −70.3955918
AS42	WTG	N 41.0380347	W −70.3735646
AT33	WTG	N 41.0188243	W −70.5714016
AT34	WTG	N 41.0191225	W −70.5493824
AT35	WTG	N 41.0194164	W −70.5273630
AT36	WTG	N 41.0197062	W −70.5053432
AT37	WTG	N 41.0199917	W −70.4833231
AT38	WTG	N 41.0202731	W −70.4613027
AT39	WTG	N 41.0205502	W −70.4392819
AT40	WTG	N 41.0208231	W −70.4172609
AT41	WTG	N 41.0210918	W −70.3952396
AU36	WTG	N 41.0030287	W −70.5049636
AU37	WTG	N 41.0033141	W −70.4829490
AU38	WTG	N 41.0035953	W −70.4609341
AU39	WTG	N 41.0038722	W −70.4389190
AU40	WTG	N 41.0041450	W −70.4169035
AV37	WTG	N 40.9866364	W −70.4825752
AV38	WTG	N 40.9869174	W −70.4605659
AV39	WTG	N 40.9871942	W −70.4385563
AW38	WTG	N 40.9702395	W −70.4601980

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the First Coast Guard District Commander in the enforcement of the safety zones.

(c) *Regulations.* No vessel may enter or remain in the safety zones described in paragraph (a) of this section except for the following:

(1) An attending vessel as defined in 33 CFR 147.20;

(2) A vessel authorized by the First Coast Guard District Commander or a designated representative.

(d) *Request for permission.* Persons or vessels seeking to enter the safety zone must request authorization from the First Coast Guard District Commander or a designated representative. If permission is granted, all persons and vessels must comply with lawful instructions of the First Coast Guard District Commander or designated representative via VHF–FM channel 16 or by phone at 617–223–1560 (First Coast Guard District Command Center).

(e) *Effective and enforcement periods.* This section is effective from June 27, 2023, through 11:59 p.m. on May 31, 2026. But it will only be enforced during active construction or other instances which may cause a hazard to navigation deemed necessary by the First Coast Guard District Commander. The First Coast Guard District Commander will make notification of the exact dates and times in advance of each enforcement period for the locations in paragraph (a) of this section to the local maritime community through the Local Notice to Mariners and will issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in response to an emergency. If the project is completed before May 31, 2026, enforcement of the safety zones will be suspended, and notice given via Local Notice to Mariners. The First Coast Guard District Local Notice to Mariners can be found at: *http://www.navcen.uscg.gov.*

Dated: April 27, 2024.

J.W. Mauger,

Rear Admiral, U.S. Coast Guard Commander, First Coast Guard District.

[FR Doc. 2024–09538 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0318]

RIN 1625–AA00

Safety Zone; Oceanside Pier, Oceanside, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 500-yard radius of the Oceanside Pier. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by first

responders and repair work to the pier. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Oceanside Fire Department Fire Chief or the Captain of the Port, Sector San Diego.

DATES: This rule is effective without actual notice from May 2, 2024 through 8 a.m. on May 4, 2024. For the purposes of enforcement, actual notice will be used from April 27, 2024, until May 2, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0318 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Shelley Turner, Sector San Diego Waterways Management Division, U.S. Coast Guard; telephone 619–278–7261, email *marineeventssd@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because a fire began on Oceanside Pier and caused extensive ongoing damage and response. Immediate action is needed to respond to the potential safety hazards associated with the emergency pier repairs and response phase. It is impracticable to publish an NPRM because we must establish this safety zone immediately.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with emergency repairs and response to the fire at Oceanside Pier.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector San Diego (COTP) has determined that potential hazards associated with emergency pier response and repairs starting April 27, 2024, will be a safety concern for anyone within a 500-yard radius of the Oceanside Pier. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the pier is being repaired.

IV. Discussion of the Rule

This rule establishes a safety zone from April 27, 2024, until 8 a.m. on May 4, 2024. The safety zone will cover all navigable waters within 500 yards of Oceanside Pier. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the pier is being repaired and first responders are assessing the condition of the pier and potential hazardous material surrounding the pier after the fire. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP, Oceanside Fire Department, or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels and persons to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct

effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 8 days that will prohibit entry within 500 yards of the Oceanside Pier. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T11–140 to read as follows:

§ 165.T11–140 Safety Zone; Oceanside Pier, Oceanside, CA.

(a) *Location.* The following area is a safety zone: All water surface to bottom encompassing a 500-yard perimeter around the Oceanside Pier in Oceanside, CA.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Diego (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF-Ch 16 or contacting the Joint Harbor Operations Center at (619) 278–7033. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

J.W. Spitler,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2024–09521 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0278]

RIN 1625–AA00

Safety Zone; Submarine Power Cables Stone Laying Project, Straits of Mackinac, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 500-yard radius of Tug Nancy Anne, Tug Champion, Tug General, Tug WM. Boyd, Tug Shirley Ann, crew boat Timmy V., barges Koko II, Koko III, Koko IV, MM 141, MM 142, D Barge 2002, D Barge 2006, and D Barge 2007. The safety zone is needed to protect the vessels while laying stones to protect exposed sections of 138kV Submarine Power Cables in the Straits of Mackinac, MI. Entry of vessels into this zone is prohibited unless specifically authorized by the Captain of the Port Northern Great Lakes.

DATES: This rule is effective from May 1, 2024, 12 a.m. through October 1, 2024, 11:59 p.m. local time. For the purposes of enforcement, actual notice will be used from May 1, 2024 until May 4, 2024. Comments and related material must be received by the Coast Guard on or before June 18, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2024–0278 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT Rebecca Simpson, Sector Northern Great Lakes Waterways Management Division, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable.

It is impracticable to publish an NPRM because this safety zone must be established by May 1, 2024, and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

For the same reasons discussed in the preceding paragraph, a 30 day delay of the effective date would be contrary to public interest because action is needed to respond to the potential safety hazards associated with the stone laying project over submarine power cables and the potential hazard from other vessels transiting the Straits of Mackinac at the same time this project is being conducted.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Northern Great Lakes (COTP) has determined that potential hazards associated with the stone laying project over submarine power cables starting May 1, 2024, will be a safety concern for anyone within a 500-yard radius of the industrial construction equipment, including Tug Nancy Anne, Tug Champion, Tug General, Tug WM. Boyd, Tug Shirley Ann, crew boat Timmy V., barges Koko II, Koko III, Koko IV, MM 141, MM 142, D Barge 2002, D Barge 2006, and D Barge 2007. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the stone laying operation is being conducted.

IV. Discussion of the Rule

This rule establishes a safety zone from 12 a.m. on May 1, 2024 until 11:59 p.m. on October 1, 2024. The safety zone will cover all navigable waters within the Mackinac Regulated Navigation Area within 500 yards of vessels and machinery being used to lay stone over exposed 138kV submarine power cables. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the stone is being laid. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, duration and location of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small, designated area of the Straits of Mackinac. Moreover, the Coast Guard will issue a Local Notice to Mariners about the safety zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In

particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone to cover all navigable waters within the Mackinac Regulated Navigation Area within 500 yards of vessels and machinery being used to lay stone over 138kV submarine power cables. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T09–0278 to read as follows:

§ 165.T09–0278 Safety Zone; Tugs Nancy Anne, Champion, General, WM. Boyd, Shirley Ann, crew boat Timmy V., and barges Koko II, Koko III, Koko IV, MM 141, MM 142, D Barge 2002, D Barge 2006, and D Barge 2007 operating in the Straits of Mackinac, MI

(a) *Location.* The following area is a safety zone: All navigable waters within 500 yards of the Tug Nancy Anne, Tug Champion, Tug General, Tug WM. Boyd, Tug Shirley Ann, crew boat Timmy V., barges Koko II, Koko III, Koko IV, MM 141, MM 142, D Barge 2002, D Barge 2006, and D Barge 2007 while laying stone over the Submarine Power cables within the Straits of Mackinac RNA.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Northern Great Lakes (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16 or telephone at (906) 635–3233. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

Dated: April 24, 2024.

J.R. Bendle,

Captain, U.S. Coast Guard, Captain of the Port Sector Northern Great Lakes.

[FR Doc. 2024–09536 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

POSTAL SERVICE

39 CFR Part 111

Commercial Mail Receiving Agencies Clarification

AGENCY: Postal Service™.

ACTION: Final rule.

SUMMARY: The Postal Service is amending *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to clarify Commercial Mail Receiving Agencies (CMRA) notary responsibilities for the addressee's signature.

DATES: *Effective date:* May 1, 2024.

FOR FURTHER INFORMATION CONTACT: Heidi Michel at (414) 239–2976, Clayton Gerber at (202) 449–8076, or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION: On December 29, 2023, the Postal Service published a notice of proposed rulemaking (88 FR 90137–90138) to clarify CMRA notary responsibilities for the addressee's signature. In response to the proposed rule, the Postal Service received one response to the notice of proposed rulemaking which included comments on multiple topics. The commenter is a business that provides remote notarial services to the public. Comments and the Postal Service responses are summarized as follows.

Comment: The commenter stated allowing CMRA owner/managers to witness the execution of PS Form 1583 remotely via a real-time audio and video session provided insufficient fraud controls.

Response: CMRAs are authorized to operate upon application to the Postal Service. This is a longstanding requirement, as the Postal Service required CMRA owner/managers to sign PS Form 1583 as far back as 1967. In 1973, the Postal Service required the CMRA owner/manager to witness the execution of PS Form 1583. It was not until 1982 that the Postal Service allowed a notary public to witness the execution of PS Form 1583. The final rule continues the practice of allowing CMRA owner/managers to witness the execution of PS Form 1583 provided the applicant presents themself along with two acceptable forms of identification in accordance with Domestic Mail Manual (DMM) sections 608.10.3–.4. The final rule permitting CMRA owners/managers to witness the execution of PS Form 1583 via real-time audio and video is consistent with these longstanding in-person practices and does not diminish any fraud controls that are already in place.

Comment: The commenter agreed with the Postal Service that remote alternatives to physical presence are necessary in today's business environment.

Response: The Postal Service agrees with the commenter that remote alternatives are desirable, which is why the final rule allows applicants to sign or confirm their signature in the physical or virtual (in real-time audio and video) presence of the CMRA owner/manager.

Comment: The commenter proposed that, if a CMRA owner/manager signed a PS Form 1583 after a virtual session with the applicant, the CMRA follow a

prescribed set of steps for the virtual session, including recording the virtual session and maintaining/storing that recording.

Response: The Postal Service has not prescribed the steps a CMRA must follow when witnessing the execution of PS Form 1583 during a virtual session, just like it has not prescribed the steps a CMRA must follow when witnessing the execution of PS Form 1583 in person. In addition, based on the Postal Service's experience, the burden and expense associated with the proposed additional recording and maintenance/storage requirements also must be balanced against need for such additional measures, and the Postal Service has not yet determined such a need exists. Consequently, the Postal Service declines to adopt the commenter's suggestion.

Comment: The commenter recognized the changes to the Rules related to Private Mail Box (PMB) applicant registration will help prevent fraud.

Response: The Postal Service shares this conclusion and expects that changes will reduce the incidence of fraud and criminal activity through PMBs at CMRAs.

Comment: The commenter suggested that by allowing the addressee to ''acknowledge'' his or her signature in the real or virtual presence of a CMRA owner/manager, the Postal Service may be unintentionally conferring notarial authority on the CMRA owner/manager.

Response: Notaries in the United States are appointed by state governments. The Postal Service has no authority to confer any notarial authority on any person, and we believe the use of the term ''acknowledge'' in relation to a CMRA owner/manager does not confer, and was not intended to confer, any such authority. Nevertheless, in the final rule, the language has been changed to address the commenter's concern that using the term ''acknowledge'' in relation to a CMRA owner/manager may be construed to confer notarial authority upon the CMRA owner/manager; accordingly the term ''acknowledge'' will be replaced with ''confirm'' in relation to a CMRA owner/manager: ''[t]he addressee must sign or confirm his or her signature in the physical or virtual (in real-time audio and video) presence of the CMRA owner or manager or authorized employee. . . .''

The Postal Service is revising DMM subsection 508.1.8.3a3 to clarify that the notary public must be commissioned in a United States state, territory, possession, or the District of Columbia and to clarify the notary public's responsibilities with respect to the addressee's signature on PS Form 1583. This clarification is needed to establish that the notary public is domestically commissioned and to address particularities of some state notary public laws that do not authorize notaries public to attest a signature. The revision allows notaries public to recognize the PS Form 1583 applicant's acknowledged signature.

The revision also clarifies that the addressee must sign or confirm his or her signature on the PS Form 1583 in the physical or virtual (in real-time audio and video) presence of the CMRA owner, manager, or authorized employee, or acknowledge his or her signature on the PS Form 1583 in the physical or virtual (in real-time audio and video) presence of a notary public.

We believe this revision will provide CMRA owners/managers with a more efficient process for accepting the PS Form 1583 and establishing mail delivery for a private mailbox (PMB) customer of the CMRA.

The Postal Service adopts the described changes to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the *Code of Federal Regulations.*

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

500 Additional Mailing Services

* * * * *

508 Recipient Services

1.0 Recipient Options

* * * * *

1.8 Commercial Mail Receiving Agencies

* * * * *

1.8.3 Delivery to CMRA

Procedures for delivery to a CMRA are as follows:

a. The following applies:

* * * * *

[Revise the first sentence of item a3 to read as follows:]

The addressee must sign or confirm his or her signature in the physical or virtual (in real-time audio and video) presence of the CMRA owner or manager or authorized employee, or acknowledge his or her signature in the physical or virtual (in real-time audio and video) presence of a notary public commissioned in a United States state, territory, possession, or the District of Columbia. * * *

* * * * *

Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2024–06989 Filed 5–1–24; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2021–0791; FRL–8599–02–OW]

RIN 2040–AG17

Water Quality Standards Regulatory Revisions To Protect Tribal Reserved Rights

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is finalizing revisions to the Clean Water Act (CWA) water quality standards (WQS) regulation to add requirements for states establishing WQS in waters where Tribes hold and assert rights to CWA-protected aquatic and aquatic-dependent resources reserved through treaties, statutes, or Executive orders.

DATES: This final rule is effective on June 3, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2021–0791. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information or other information whose

disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jennifer Brundage or Kelly Gravuer, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1265 or (202) 566–2946; email address: *brundage.jennifer@epa.gov* or *gravuer.kelly@epa.gov*.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

I. Executive Summary

Many Tribes hold rights to natural and cultural resources that are reserved, either expressly or implicitly, through treaties, statutes, or executive orders. Environmental regulatory schemes have often failed to recognize or protect such rights. This places Tribal members who rely on these vital resources for sustenance and to support longstanding cultural practices at disproportionate risk. This rule establishes a framework for how Tribal reserved rights, as defined in this final rule, must be considered in establishing WQS. In this final rule, the EPA is amending the Federal WQS regulation at 40 CFR part 131 to: (1) define Tribal reserved rights for purposes of that regulation; (2) establish and clarify the responsibilities of states [1] with regard to Tribal reserved rights in the WQS context; and (3) establish and clarify the EPA's related responsibilities and oversight role.

This rule defines Tribal reserved rights, for purposes of 40 CFR part 131, as ''any rights to CWA-protected aquatic and/or aquatic-dependent resources reserved by right holders, either expressly or implicitly, through Federal treaties, statutes, or executive orders.'' Pursuant to its CWA authority, the EPA is defining ''Tribal reserved rights,'' for purposes of this regulation for use in WQS actions. In defining ''Tribal reserved rights'' for purposes of the EPA's WQS regulation, the EPA is not purporting to establish or interpret rights that may exist, or the scope of such rights, under a Federal treaty or other sources of Federal law. Rather, this definition provides that rights reserved by treaty, statute, or executive order to aquatic and/or aquatic-dependent resources that also fall within the ambit of resources protected under the CWA are within the scope of potentially applicable rights for purposes of this rule. Whether a Tribal reserved right, as defined in this rule, will result in new or revised WQS is a case-by-case inquiry that will be undertaken in accordance with the provisions of this final rule.

The EPA has previously addressed Tribal reserved rights in specific WQS actions. In this final rule, the agency is amending the existing WQS regulation to explicitly address how the EPA and states must consider applicable Tribal reserved rights in establishing WQS. By doing so, the agency is providing greater transparency and clarifying its expectations for WQS in waters where Tribal reserved rights apply.

The rule requires that if a Tribe asserts a Tribal reserved right in writing to a state and the EPA for consideration in establishment of WQS, the state must, to the extent supported by available data and information: (1) take into consideration the use and value of its waters for protecting the Tribal reserved right in adopting or revising designated uses; (2) take into consideration the anticipated future exercise of the Tribal reserved right unsuppressed by water quality in establishing relevant WQS; and (3) establish water quality criteria to protect the Tribal reserved right where the state has adopted designated uses that either expressly incorporate protection of the Tribal reserved right or encompass the right. This latter requirement includes developing criteria to protect right holders using at least the same risk level (*e.g.,* cancer risk level, hazard quotient, or illness rate) as the state would otherwise use to develop criteria to protect the state's general population (*i.e.,* non-right holders), paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right. The EPA will be subject to the same requirements when promulgating Federal WQS.

The rule commits the EPA to: (1) providing assistance to both states and right holders in evaluating Tribal reserved rights, upon request, to the extent practicable; and (2) initiating the Tribal consultation process with any right holders that have asserted their rights for consideration in establishment of WQS.

The rule amends the list of minimum requirements for state submissions of new or revised WQS to the EPA for review pursuant to CWA section 303(c) to include, where applicable, submission of information provided by right holders about relevant Tribal reserved rights and of documentation indicating how the state considered that information.

The rule revises the list of factors that the EPA considers in determining whether state-adopted new or revised WQS are consistent with CWA section 303(c) and 40 CFR part 131 to include, where applicable, whether WQS are consistent with the requirements for states established by this rule.

Finally, the rule modifies the procedures for state review and revision of WQS to require that the triennial review process include any new information available about Tribal reserved rights.

[1] Pursuant to 40 CFR 131.3(j), ''states'' include the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, and Indian Tribes that the EPA determines to be eligible for purposes of the WQS program.

II. General Information

A. Does this action apply to me?

States responsible for administering or overseeing water quality programs may be affected by this final rule, as they may need to consider and implement new provisions, or revise existing provisions, in their WQS. Federally recognized Indian Tribes [2] with reserved rights [3] may also be affected by this final rule. Entities that are subject to CWA regulatory programs, such as industrial facilities and municipalities that manage stormwater, separate sanitary, or combined sewer systems could be indirectly affected by this final rule. Categories and entities that could potentially be affected include the following:

TABLE 1—DISCHARGERS POTENTIALLY AFFECTED BY THIS FINAL RULE

Category	Examples of potentially affected entities
Industry	Industrial point sources that discharge pollutants.
Municipalities, including those with stormwater or combined sewer system outfalls.	Publicly owned treatment works or similar facilities responsible for managing stormwater, separate sanitary, or combined sewer systems that discharge pollutants.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be indirectly affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How did the EPA develop this final rule?

In developing this final rule, the EPA carefully considered the input from Tribes received during a 90-day Tribal consultation and coordination period following publication of the proposed rulemaking in the **Federal Register** on December 5, 2022, as well as public comments received from interested parties during a concurrent 90-day public comment period.[4] In addition, the EPA held two online public hearings on January 24 and 31, 2023, to discuss the contents of the proposed rulemaking and accept verbal public comments.

One hundred sixty-two organizations and individuals submitted comments on a range of issues. Some comments addressed issues beyond the scope of the rulemaking, and thus the EPA did not consider them in finalizing this rule. In this preamble, the EPA explains how it responded to certain comments received on aspects of the proposal. For a complete summary of all comments received and the EPA's responses, see the EPA's Response to Comments document in the official public docket. For a summary of input received from Tribes during the Tribal consultation and coordination period, please see section VI.F of this preamble.

III. Statutory and Regulatory Background

A. Clean Water Act

The CWA establishes the basic structure for regulating pollutant discharges into waters of the United States. In the CWA, Congress established the national objective to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters,'' and to achieve ''wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water'' (CWA sections 101(a) and 101(a)(2)).

CWA section 303(c) directs states to adopt WQS for waters of the United States. The core components of WQS are designated uses, water quality criteria, and antidegradation requirements. Designated uses establish the environmental objectives for a water body, such as public drinking water supply, propagation of fish, shellfish and wildlife, or recreation. Water quality criteria define the minimum conditions necessary to achieve those environmental objectives. Antidegradation requirements maintain and protect water quality that has already been achieved.

WQS serve as the basis for several CWA programs, including:

- Water body assessments, identification of impaired waters, and development of total maximum daily loads (TMDLs) under CWA sections 305(b) and 303(d);
- Certifications of Federal licenses and permits under CWA section 401;
- Water quality-based effluent limits in National Pollutant Discharge Elimination System (NPDES) permits issued by approved state programs or by the EPA under CWA section 402; and
- Permits for dredged or fill material under CWA section 404.

Section 303(c)(2)(A) of the CWA provides that ''[water quality] standards shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this chapter. Such standards shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.'' CWA section 303(c)(2)(A) and the EPA's implementing regulation at 40 CFR part 131 require, among other things, that a state's WQS specify appropriate designated uses of the waters, and water quality criteria to protect those uses.[5] Such criteria must be based on sound scientific rationale, must contain sufficient parameters to protect the designated use, must support the most sensitive use where multiple use designations apply, and may be expressed in either narrative or numeric form.[6] In addition, 40 CFR 131.10(b) provides that ''[i]n designating uses of a water body and the appropriate criteria for those uses, the state shall take into

[2] *See* Federally Recognized Indian Tribe List Act of 1944, 25 U.S.C. 479a. The current list can be found at 88 FR 2112–2116 (January 12, 2023).

[3] The EPA is defining ''Tribal reserved rights'' for the purposes of 40 CFR part 131 as ''any rights to CWA-protected aquatic and/or aquatic-dependent resources reserved by right holders, either expressly or implicitly, through Federal treaties, statutes, or executive orders.''

[4] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361 (December 5, 2022).

[5] *See* 40 CFR 131.10.

[6] *See* 40 CFR 131.11(a) and (b). Special requirements apply to ''priority toxic pollutants.'' CWA section 303(c)(2)(B) requires states to adopt numeric criteria, where available, for all toxic pollutants listed pursuant to CWA section 307(a)(1) for which the EPA has published CWA section 304(a) criteria, as necessary to support the states' designated uses. ''Priority toxic pollutants'' are identified in 40 CFR part 423, Appendix A—126 Priority Pollutants. Consistent with 40 CFR 131.11(a)(2), where a state or authorized Tribe adopts narrative criteria for priority pollutants to protect designated uses, it must also provide information identifying the method by which it intends to regulate point source discharges of priority pollutants in water quality-limited waters based on such narrative criteria.

consideration the water quality standards of downstream waters and ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.''

Antidegradation requirements provide a framework for maintaining and protecting water quality that has already been achieved.[7] States can also choose to include general policies in their WQS that affect WQS implementation, such as WQS variance policies and mixing zone policies.[8]

States are required to hold a public hearing to review applicable WQS at least once every three years (''triennial review'') and, if appropriate, to revise standards or adopt new standards.[9] Any new or revised WQS must be submitted to the EPA for review and approval or disapproval.[10] CWA section 303(c)(4)(B) authorizes the Administrator to independently determine that a new or revised standard is necessary to meet CWA requirements, referred to as an Administrator's Determination.

CWA section 501(a) authorizes the Administrator to ''prescribe such regulations as are necessary to carry out his functions under this chapter.'' CWA section 511(a)(3) provides that the Act ''shall not be construed as . . . affecting or impairing the provisions of any treaty of the United States.''

B. Tribal Reserved Rights

1. Overview of Tribal Reserved Rights in Federal Law

The EPA recognizes that many federally recognized Tribes hold rights to use and access natural and cultural resources, and that exercise of these rights is an intrinsic part of Tribal life and is of deep cultural, economic, and subsistence importance to Tribes.[11] The Supreme Court has described Tribal reserved rights to fish and access fishing locations as ''not much less necessary to the existence of the Indians than the atmosphere they breathed[.]'' [12] Such rights are ''reserved'' by Tribes, because, as the U.S. Supreme Court has explained, treaties are ''not a grant of rights to the Indians, but a grant of rights from them, a reservation of those not granted.'' [13] As described further below, these rights may be recognized in treaties, statutes, or Executive orders, and may be explicit or implied.

The U.S. Constitution defines treaties as part of the supreme law of the land, with the same legal force as Federal statutes.[14] From 1778 to 1871, U.S. relations with Tribes were defined and conducted largely through treaty-making. In 1871, Congress stopped making treaties with Tribes,[15] and subsequent agreements between Tribes and the Federal Government were instead generally memorialized through Executive orders or statutes, such as congressionally enacted Indian land claim settlements, with equally binding effect.[16] As one court explained, generally ''it makes no difference whether . . . [Tribal] rights derive from treaty, statute or executive order, unless Congress has provided otherwise.'' [17] Pursuant to the Constitution's Supremacy Clause, treaties and statutes also bind states.[18]

Courts generally adhere to several guiding principles, known as the ''Indian canons of construction,'' in interpreting treaties and other Federal legal instruments regarding Indian Tribes. In accordance with these canons, ''Indian treaties are to be interpreted liberally in favor of the Indians, and any ambiguities are to be resolved in their favor.'' [19] Further, treaties ''are to be construed as the Indians would have understood them'' at the time of signing.[20] Although Congress may abrogate Indian treaty rights, those rights remain absent clear evidence of congressional intent.[21] While these Indian canons of construction originated in the context of treaty interpretation by Federal courts, courts have also applied the canons in other contexts,[22] including determining the scope of Tribes' rights under statutes or Executive orders setting aside land for Tribes.[23] Some Tribes have treaty rights

[7] *See* 40 CFR 131.12.

[8] *See* 40 CFR 131.13.

[9] *See* CWA section 303(c)(1); 40 CFR 131.20(a).

[10] *See* CWA section 303(c)(2)(A) and (c)(3); 40 CFR 131.21(a).

[11] 2021 Memorandum of Understanding Regarding Interagency Coordination and Collaboration for the Protection of Tribal Treaty Rights and Reserved Rights. Available online at *https://www.doi.gov/sites/doi.gov/files/interagency-mou-protecting-tribal-treaty-and-reserved-rights-11-15-2021.pdf.*

[12] *United States* v. *Winans,* 198 U.S. at 381.

[13] *Id.*

[14] U.S. Constitution, Art. VI, cl. 2 (''This constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any State to the contrary notwithstanding.'').

[15] *See* Act of March 3, 1871, section 1, 16 Stat. 544 (codified as carried forward at 25 U.S.C. 71).

[16] *See* Cohen's Handbook of Federal Indian Law section 18.02 (Nell Jessup Newton et al eds., 2005) (''Statutes and agreements that are ratified by Congress become, like treaties, the supreme law of the land'').

[17] *Parravano* v. *Babbitt,* 70 F.3d 539, 545 (9th Cir. 1995), cert. denied, 518 U.S. 1016 (1996); *see also United States* v. *Dion,* 476 U.S. 734, 745, n.8 (''Indian reservations created by statute, agreement, or executive order normally carry with them the same implicit hunting rights as those created by treaty.'').

[18] *Antoine* v. *Washington,* 420 U.S. 194, 205 (1975) (like a treaty, when Congress by statute ratifies an agreement that reserves Tribal rights, ''State qualification of the rights is precluded by force of the Supremacy Clause, and neither an express provision precluding state qualification nor the consent of the State [is] required''); *U.S.* v. *Washington,* 853 F.3d 946, 966 (9th Cir. 2017) (Holding that ''in building and maintaining barrier culverts within the Case Area, Washington has violated, and is continuing to violate, its obligation to the Tribes under the Treaties.'') *aff'd,* 138 S.Ct. 1832 (per curiam); *Skokomish Indian Tribe* v. *United States,* 410 F.3d 506, 512 (9th Cir. 2005) (Treaties ''constitute the 'supreme law of the land' '' and have ''been found to provide rights of action for equitable relief against non-contracting parties,'' and such equitable relief ''ensures compliance with a treaty; that is, it forces state governmental entities and their officers to conform their conduct to federal law.''); *see also Minnesota* v. *Mille Lacs Band of Chippewa Indians,* 526 U.S. 172, 204 (1999) (noting that ''[a]lthough States have important interests in regulating wildlife and natural resources within their borders, this authority is shared with the Federal Government when the Federal Government exercises one of its enumerated constitutional powers, such as treaty making,'' and accordingly, the treaty in that case gave the Chippewa Tribe ''the right to hunt, fish, and gather in the ceded territory free of . . . state, regulation.'').

[19] *Mille Lacs,* 526 U.S. at 200 (internal citations omitted); *see also County of Oneida* v. *Oneida Indian Nation,* 470 U.S. 226, 247 (1985) (''it is well established that treaties should be construed liberally in favor of the Indians with ambiguous provisions interpreted for their benefit'').

[20] *Mille Lacs,* 526 U.S. at 196 (''[W]e interpret Indian treaties to give effect to the terms as the Indians themselves would have understood them.''); *Jones* v. *Meehan,* 175 U.S. 1, 11 (1899) (A ''treaty must therefore be construed, not according to the technical meaning of its words to learned lawyers, but in the sense in which they would naturally be understood by the Indians.'').

[21] *Mille Lacs,* 526 U.S. at 202 (''Congress may abrogate Indian treaty rights, but it must clearly express its intent to do so.''); *United States* v. *Dion,* 476 U.S. 734, 739–40 (1986) (noting that in finding congressional intent to abrogate ''[w]hat is essential is clear evidence that Congress actually considered the conflict between its intended action on the one hand and the Indian treaty rights on the other, and chose to resolve that conflict by abrogating the treaty'').

[22] *See e.g., Hagen* v. *Utah,* 510 U.S. 399, 423–24 (1994) (''For more than 150 years, we have applied this canon in all areas of Indian law to construe congressional ambiguity or silence, in treaties, statutes, Executive orders, and agreements, to the Indians' benefit.''); *County of Yakima* v. *Confederated Tribes,* 502 U.S. 251, 268–69 (1992) (quoting *Montana* v. *Blackfeet Tribe,* 471 U. S. 759, 766 (1985)) (''statutes are to be construed liberally in favor of the Indians, with ambiguous provisions interpreted to their benefit''); *Alaska Pacific Fisheries Co.* v. *U.S.,* 248 U.S. 78, 89 (1918) (''statutes passed for the benefit of dependent Indian Tribes or communities are to be liberally construed, doubtful expressions being resolved in favor of the Indians''); *but see Penobscot Nation* v. *Frey,* 3 F.4th 484, 502 (1st Cir. 2021) (holding that the Indian canons of construction were inapplicable to statutes settling Indian land claims in Maine).

[23] *See Winters* v. *United States,* 207 U. S. 564, 576–577 (1908) (applying the canons and holding that the Tribe was entitled to federally reserved rights to the Milk River); *Parravano,* 70 F.3d at 544 (applying the canons to determine the scope of

that are no longer enforceable because they have been abrogated or otherwise superseded by Congress in later Federal statutes.[24] In addition, some Tribes negotiated treaties with the U.S. government that were not ratified.[25]

Rights reserved to Tribes and reflected in treaties and other laws may apply in Indian country as well as outside of Indian country [26] and may be express or implied.[27] For example, in certain states in the Great Lakes region, Tribal reserved rights include hunting, fishing, and gathering rights both within Tribes' reservations and outside these reservations in specific areas that the Tribes ceded to the Federal Government.[28] In the Pacific Northwest, treaties explicitly reserved to many Tribes rights to fish in their ''usual and accustomed'' fishing grounds and at stations both within and outside their reservation boundaries and to hunt and gather throughout their traditional territories.[29] In addition to Tribes whose rights are reserved through treaties, other Tribes have statutorily reserved rights. For example, Tribes in Maine have statutorily reserved rights to practice traditional sustenance lifeways such as fishing in certain waters.[30]

2. Tribal Reserved Rights and Water Quality Standards

As explained in the proposed rulemaking, the EPA has previously addressed reserved rights held by Tribes in state-specific WQS actions. In this final rule, the agency is including additional information on its prior approaches to addressing how WQS should account for such rights, consistent with comments requesting that the agency provide a fuller description of how the requirements in this final rule differ from the agency's prior actions.

From 2015 through 2017, the EPA took actions related to three state WQS submittals where affected Tribes had asserted that they held reserved fishing rights. In those actions, the EPA ''harmoniz[ed] the requirements of the CWA with the terms of'' applicable statutes (in Maine) and treaties (in Washington and Idaho) and found that, based on that harmonization, the WQS submitted by those states were not sufficiently protective of the applicable reserved rights.[31] First, in 2015, the EPA disapproved certain human health criteria adopted by the State of Maine because they did not adequately account for Tribal members' rights to fish for sustenance, reserved under applicable Federal statutes. The agency explained that the initial step in reaching that outcome was to ''harmonize the CWA requirement that WQS must protect uses with the fundamental purpose for which land was set aside for the Tribes under the Indian settlement acts in Maine.'' [32] The agency explained that, pursuant to that harmonization, the ''EPA interprets the State's 'fishing' designated use, as applied in Tribal waters, to mean 'sustenance' fishing.'' [33]

Similarly in 2016, in promulgating human health criteria for the State of Washington, the EPA noted that most waters covered by the state's WQS were subject to Federal treaties that reserved Tribal fishing rights. The agency again harmonized the applicable treaties with the CWA and the EPA's WQS regulation and found that it was appropriate to interpret the state's relevant designated use to ''include or encompass a subsistence fishing component.'' [34] The EPA articulated a similar position in a January 2017 letter to Idaho regarding human health criteria submitted by Idaho in December 2016, reiterating the ''need to consider treaty-reserved fishing rights and harmonize those rights with the [CWA] when deriving criteria necessary to protect Idaho's designated uses for fishing.'' [35]

In each of these three actions, the EPA harmonized the CWA with the specific treaties or statutes by interpreting the relevant state uses. Based on that interpretation of each state's respective use as protecting applicable reserved rights, the agency concluded that in order to protect those uses, each state's human health criteria needed to protect Tribal members exercising the right to the same level as each state's respective general population, and the fish consumption rates used to derive those criteria needed to reflect unsuppressed consumption by that state's Tribal fish consumers.[36]

Tribes' reserved fishing rights under Executive orders and a statute).

[24] U.S. Constitution, Art. II, section 2, cl. 2; *S. Dakota* v. *Bourland,* 508 U.S. 679, 690 (1993) (Statutory language providing that ''the sum paid by the Government to the Tribe for former trust lands taken for the Oahe Dam and Reservoir Project, 'shall be in final and complete settlement of all claims, rights, and demands' of the Tribe or its allottees'' made clear that the Tribe no longer retained its treaty right to regulate hunting and fishing); *Dion,* 476 U.S. at 739 (While Congress has the power to abrogate a treaty, ''the intention to abrogate or modify a treaty is not to be lightly imputed . . . Indian treaty rights are too fundamental to be easily cast aside.''); *U.S.* v. *McAlester,* 604 F.2d 42, 62–63 (10th Cir. 1979) (describing the history of the Choctaw Tribe's treaty-making with the United States, including several treaties in the late 1700s and early 1800s providing rights to lands that were later lost due to the Indian Removal Act of 1830, which ''finally forced the Choctaw Nation to agree . . . to relinquish all its lands east of the Mississippi River and to settle on lands west of the Arkansas Territory'').

[25] Bureau of Indian Affairs, Frequently Asked Questions, available at *https://www.bia.gov/frequently-asked-questions* (noting that ''[t]he treaties that were made often contain commitments that have either been fulfilled or subsequently superseded by Congressional legislation''); *Robinson* v. *Jewell,* 790 F.3d 910, 918 (9th Cir. 2015) (holding that an 1851 Treaty was never ratified by the Senate and thus carries ''no legal effect.'').

[26] Indian country is defined at 18 U.S.C. 1151 as: (a) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

[27] *See Menominee Tribe of Indians* v. *U.S.,* 391 U.S. 404, 406, (1968) (Noting that ''nothing was said in the 1854 treaty about hunting and fishing rights,'' but holding that such rights were implied, as the treaty phrase '''to be held as Indian lands are held' includes the right to fish and to hunt.''); *Makah Indian Tribe* v. *Quileute Indian Tribe,* 873 F.3d 1157, 1160 (9th Cir. 2017), *cert. denied* 139 S. Ct. 106 (2018) (Affirming district court finding that, based on historical and linguistic evidence, that use of the term ''fish'' in the Treaty of Olympia encompassed whales and seals).

[28] *See e.g.,* Treaty with the Chippewas, 1837, art. 5, 7 Stat. 536 (Tribes retained ''[t]he privilege of hunting, fishing, and gathering the wild rice, upon the lands, the rivers and the lakes included in the territory ceded''); *Minnesota* v. *Mille Lacs Band of Chippewa Indians,* 526 U.S. 172 (1999).

[29] *See, e.g.,* Treaty with the Nez Perces, 1855, art. 3, 12 Stat. 957; Treaty with the Nisquallys, etc., 1854, art. 3, 10 Stat. 1132 (Treaty of Medicine Creek).

[30] *See, e.g.,* Maine Implementing Act, 30 M.R.S 6207(4), (9).

[31] *See* Letter from H. Curtis Spalding, Regional Administrator, EPA Region 1, to Patricia W. Aho, Commissioner, Maine Department of Environmental Protection, ''Re: Review and Decision on Water Quality Standards Revisions'' (February 2, 2015); Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 FR 85417, 85424 (November 28, 2016); Letter from Dennis McLerran, Regional Administrator, EPA Region 10, to John Tippets, Director, Idaho Department of Environmental Quality, ''The EPA's Preliminary Review of DEQ'S December 13, 2016 Submittal of New and Revised Human Health Criteria'' at 10 (January 19, 2017).

[32] Letter from H. Curtis Spalding, Regional Administrator, EPA Region 1, to Patricia W. Aho, Commissioner, Maine Department of Environmental Protection, ''Re: Review and Decision on Water Quality Standards Revisions'' (February 2, 2015).

[33] *Id.*

[34] 81 FR 85417, 85424 (November 28, 2016).

[35] Letter from Dennis McLerran, Regional Administrator, EPA Region 10, to John Tippets, Director, Idaho Department of Environmental Quality, ''The EPA's Preliminary Review of DEQ'S December 13, 2016 Submittal of New and Revised Human Health Criteria'' at 10 (January 19, 2017).

[36] *See* Letter from H. Curtis Spalding, Regional Administrator, EPA Region 1, to Patricia W. Aho, Commissioner, Maine Department of Environmental Protection, ''Re: Review and Decision on Water Quality Standards Revisions'' (February 2, 2015); Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 FR 85417, 85424 (November 28, 2016); Letter from Dennis McLerran, Regional Administrator, EPA Region 10, to John Tippets, Director, Idaho Department of

Continued

These actions followed a December 2014 memorandum from the EPA Administrator Gina McCarthy that discussed the EPA's role with respect to Tribal treaty rights.[37] This memorandum was issued to commemorate the 30th anniversary of the EPA's 1984 Indian Policy, which addressed many issues related to the EPA's relationship with federally recognized Tribes and implementation of the EPA's statutes in Indian country, but did not expressly address the EPA's consideration of Tribal treaty and other reserved rights.[38] In pertinent part, the 2014 memorandum provides that the ''EPA has an obligation to honor and respect Tribal rights and resources protected by treaties,'' and that the ''EPA must ensure its actions do not conflict with Tribal treaty rights.'' [39] In 2016, as part of the agency's efforts to implement the memorandum, the EPA issued an addendum to its Tribal consultation policy entitled ''Guidance for Discussing Tribal Treaty Rights'' with the purpose of enhancing the EPA's consultations where agency actions may affect Tribal treaty rights.[40] The goal of this document was to help ensure that the EPA's actions do not conflict with treaty rights, and that the EPA is fully informed as it seeks to implement its programs to further protect Tribal treaty rights and resources when it has discretion to do so.[41] Even before this guidance was issued in 2016, the EPA routinely discussed Tribal treaty rights during consultation with Tribes. For example, in the agency's actions in Maine, Washington, and Idaho with regard to WQS, the EPA undertook extensive consultation with the federally recognized Tribes in those states which included, consistent with the objectives of that guidance, gathering information regarding relevant reserved rights.[42]

Although the agency did not rescind the Memorandum and Guidance for Discussing Tribal Treaty Rights, in subsequent state-specific WQS actions taken in 2019 the agency disavowed the approach to protecting Tribal reserved rights that the EPA had set forth in the Maine (2015) and Washington (2016) actions, as well as in the EPA's 2017 letter to the State of Idaho regarding protection of applicable treaty rights in that state.[43] In 2019, the EPA approved Idaho's human health criteria, despite its prior expression of concern that the state's WQS did not sufficiently protect applicable Tribal reserved rights.[44] In its approval, the EPA acknowledged the approach the agency had applied in Maine and Washington in 2015 and 2016 but noted that that approach ''had not been promulgated in any nationally applicable rule or articulated in any national recommended guidance,'' and had not gone through public comment prior to the agency applying it in those states.[45] To the extent that assertion implied a procedural deficiency, that assertion is now moot because the agency is establishing, through this rule, regulatory requirements addressing how WQS are to reflect consideration and protection of applicable Tribal reserved rights, as defined by this rule.

The legal basis for the requirements in this final rule differs in an important respect from the legal underpinnings of the agency's WQS disapprovals in Maine and Washington in 2015 and 2016, respectively, and the EPA's 2017 letter to Idaho regarding its WQS. Namely, as explained above, the legal rationale for those actions was harmonizing the CWA and existing regulatory requirements with specific Federal treaties and statutes and concluding that, read together, the CWA and WQS regulatory requirements and the respective treaties and statutes justified interpreting existing state designated uses to encompass relevant Tribal fishing rights.[46] As explained in section III.C of this preamble, the EPA's authority to add the requirements set forth in this final rule does not derive from harmonizing a specific treaty, statute, or Executive order with the CWA. Rather, the regulatory requirements in this final rule are an exercise of the EPA's CWA oversight function provided by Congress in CWA section 303(c).

While the legal basis for these requirements differs from that of the EPA's 2015–2017 actions in Maine, Washington, and Idaho, there are similarities between the substantive elements of this final rule and what the EPA found would protect applicable Tribal reserved rights in those actions. Namely, in those actions, the EPA found that the applicable human health criteria needed to protect Tribal members to the same risk level as the states' general populations at an unsuppressed fish consumption rate. In this rule, as described in section IV of this preamble, the EPA is explicitly adding similar, though not identical, carefully tailored requirements regarding uses, suppression, and risk level in its regulation governing the establishment of WQS that reflect extensive input from states, Tribes, and the regulated community and are grounded in the CWA and consistent with the EPA's longstanding approach to overseeing state WQS.

C. EPA Authority

1. CWA Statutory Authority for This Final Rule

The EPA's authority for this rule derives primarily from section 303(c) of the CWA. In CWA section 303(c),

Environmental Quality, ''The EPA's Preliminary Review of DEQ'S December 13, 2016 Submittal of New and Revised Human Health Criteria'' at 10 (January 19, 2017).

[37] U.S. EPA, Memorandum, *Commemorating the 30th Anniversary of the EPA's Indian Policy* (December 1, 2014), available at *https://www.epa.gov/sites/production/files/2015-05/documents/indianpolicytreatyrightsmemo2014.pdf.*

[38] *Id. See also* U.S. EPA, *EPA Policy for the Administration of Environmental Programs on Indian Reservations* (November 8, 1984), available at *https://www.epa.gov/sites/default/files/2015-04/documents/indian-policy-84.pdf.*

[39] U.S. EPA, Memorandum, *Commemorating the 30th Anniversary of the EPA's Indian Policy* (December 1, 2014), available at *https://www.epa.gov/sites/production/files/2015-05/documents/indianpolicytreatyrightsmemo2014.pdf.*

[40] U.S. EPA, *EPA Policy on Consultation and Coordination with Indian Tribes: Guidance for Discussing Tribal Treaty Rights* (February 2016), available at *https://www.epa.gov/sites/default/files/2016-02/documents/tribal_treaty_rights_guidance_for_discussing_tribal_treaty_rights.pdf.*

[41] *Id.*

[42] *See* U.S. EPA Region 1, Responses to Public Comments Relating to Maine's January 14, 2013, Submission to EPA for Approval of Certain of the State's New and Revised Water Quality Standards (WQS) That Would Apply in Waters Throughout Maine, Including Within Indian Territories or Lands (January 30, 2015), at 1540 (describing Tribal consultation); 81 FR 85417 at 85435 (November 28, 2016).

[43] *See e.g.,* U.S. EPA, Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to John Tippets, Director, Department of Environmental Quality, Re: EPA's Approval of Idaho's New and Revised Human Health Water Quality Criteria for Toxics and Other Water Quality Standards Provisions (April 4, 2019) at 10; U.S. EPA, Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Department of Ecology, Re: EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria (May 10, 2019), at 21.

[44] U.S. EPA, Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to John Tippets, Director, Department of Environmental Quality, Re: EPA's Approval of Idaho's New and Revised Human Health Water Quality Criteria for Toxics and Other Water Quality Standards Provisions (April 4, 2019) at 10.

[45] *Id.* at 10–11.

[46] *See* Letter from H. Curtis Spalding, Regional Administrator, EPA Region 1, to Patricia W. Aho, Commissioner, Maine Department of Environmental Protection, ''Re: Review and Decision on Water Quality Standards Revisions'' (February 2, 2015); Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 FR 85417, 85424 (November 28, 2016); Letter from Dennis McLerran, Regional Administrator, EPA Region 10, to John Tippets, Director, Idaho Department of Environmental Quality, ''The EPA's Preliminary Review of DEQ'S December 13, 2016 Submittal of New and Revised Human Health Criteria'' at 10 (January 19, 2017).

Congress set forth statutory requirements governing the establishment of WQS and tasked the EPA with overseeing state implementation of and compliance with those requirements.[47] Congress established a structure whereby states are responsible for establishing WQS applicable to their waters, obtaining the EPA's approval of those standards, and reviewing their standards at least once every three years. Congress also provided direction regarding the nature of such standards. As noted previously, CWA section 303(c) provides that WQS ''shall be such as to protect the public health or welfare, enhance the quality of water, and serve the purposes of'' the Act.[48] It further provides that WQS ''shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.'' [49] State discretion to determine appropriate standards for their waters is not unfettered.[50] While CWA section 303(c) directs states to establish WQS in the first instance, Congress expressly gave the EPA the responsibility to review state WQS, and to disapprove them and promulgate Federal standards if state standards do not meet the applicable requirements of the Act.[51] The ''EPA is permitted—and in fact statutorily required—to scrutinize a state's water quality standards.'' *Id.* The Act ''requires EPA to determine whether the standard is 'consistent with' the Act's requirements.'' [52]

To inform the EPA's statutorily mandated review of state WQS, the EPA's implementing regulation at 40 CFR part 131 specifies requirements for state WQS submissions. This rule, like the existing requirements in 40 CFR part 131, is issued in exercise of the EPA's oversight authority in CWA section 303(c) and is in accordance with the EPA's longstanding general approach to implementing CWA section 303(c), which is to ''use standards as a basis of restoring and maintaining the integrity of the Nation's waters.'' [53] The operative requirements in this rule are set forth in 40 CFR 131.9 and explained in detail in section IV of this preamble. This explanation includes the EPA's authority to add the specific requirements in 40 CFR 131.9.

While CWA section 303(c) is the substantive source of authority for this rule, CWA section 501 authorizes the agency to prescribe regulations as necessary to carry out the Administrator's functions under the Act,[54] and the EPA has from time to time issued regulations necessary to carry out its functions under CWA section 303(c). Those regulations, codified at 40 CFR part 131, provide a framework for implementing CWA section 303(c) and related sections, translating the statutory provisions, processes, and directives in CWA section 303(c) into specific requirements consistent with the statutory scheme. This rule adds to that existing framework.

The EPA received many comments asserting that the EPA lacks authority to promulgate the requirements in this rule. The EPA disagrees. The statutory bases for the EPA's action are outlined above and explained in detail in section IV of this preamble. Specific contentions that the EPA lacks authority for particular aspects of this rule are addressed in section IV of this preamble. As described further in section IV of this preamble, these regulatory changes are designed to ensure that WQS will in fact ''protect the public health and welfare,'' including the health and welfare of right holders, and otherwise serve the purposes of the Act, and that consideration of the waters' ''use and value'' does not overlook right holders' use pursuant to the identified reserved rights.[55]

Some commenters asserted that the EPA improperly relied on CWA section 511 as a grant of regulatory authority. These commenters assert that CWA section 511 is a savings clause and an interpretative limitation on the CWA as a whole rather than a basis for these requirements. The EPA is clarifying that, contrary to the characterizations in these comments, the agency is not relying on CWA section 511(a)(3) as a source of rulemaking authority.

In the proposed rulemaking, the agency acknowledged that there may be instances where a later-enacted statutory provision intentionally limits federally reserved rights, citing to *United States* v. *Dion,* 476 U.S. 734, 739–40 (1986). In that case, the Supreme Court applied the principle that courts will not find that Congress intends to abrogate a treaty right absent an indication of clear Congressional intent to do so, holding that ''Congressional intent to abrogate Indian treaty rights to hunt bald and golden eagles is certainly strongly suggested on the face of the Eagle Protection Act,'' the statute at issue in that decision.[56] The EPA's reference to CWA section 511(a)(3) in the proposed rulemaking was to illustrate that there is no such similar Congressional intent to abrogate treaty rights in the CWA, given that in section 511 Congress explicitly provided that the Act ''shall not be construed as . . . affecting or impairing the provision of any treaty of the United States.'' [57] While it is not an affirmative grant of authority, CWA section 511(a)(3) nonetheless supports the agency's approach in adding these requirements, which, in practice, will aid in ensuring that WQS will not ''affect[ ] or impair[ ] the provisions'' of treaties reserving rights to aquatic or aquatic-dependent resources. Indeed, the requirements in this rule will help to ensure that future WQS reflect consideration of and provide protection for treaty rights, where applicable. As explained above, rather than relying on CWA section 511(a)(3) as an affirmative source of authority for this rule, the EPA's substantive authority to promulgate this rule derives from CWA section 303(c).

2. Legal Significance of Applicable Treaties, Statutes, or Executive Orders In Informing This Final Rule's Requirements

In this final rule, the EPA is clarifying that these requirements are not based on any one treaty, statute, or Executive order, but rather reflect the EPA's judgment regarding the necessary considerations and level of protection appropriate under the CWA where such rights apply. In the proposed rulemaking, the EPA explained that, in exercising its CWA section 303(c) authority, the EPA is ensuring that its actions are consistent with treaties, statutes, Executive orders, and other sources of Federal law reflecting reserved rights of Tribes. The EPA received some public comments reflecting confusion regarding how the interpretation of a relevant treaty, statute, or Executive order relates to the

[47] *See* CWA section 303(c)(2)(A), 303(c)(3) and (4).

[48] *See* CWA section 303(c)(2)(A).

[49] *Id.*

[50] *See El Dorado Chem. Co.* v. *EPA,* 763 F.3d 950, 956 (8th Cir. 2014).

[51] *See* CWA section 303(c)(3) and 4.

[52] *See Miss Comm'n on Natural Res.* v. *Costle,* 625 F.2d 1269, 1275–76 (5th Cir. 1980).

[53] *Water Quality Standards Regulation,* 48 FR 51400 (November 8, 1983).

[54] *See also E. I. du Pont de Nemours & Co.* v. *Train,* 430 U.S. 112, 132 (1977) (''501(a) . . . gives EPA the power to make 'such regulations as are necessary to carry out' its functions'').

[55] *See* CWA section 303(c)(2)(A).

[56] *Dion,* 476 U.S. at 739–40.

[57] *See* CWA section 511(a)(3); *Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74379 (December 5, 2022).

rule's requirements. Specifically, these commenters stated that the EPA was placing an undue reliance on judicial decisions in which courts have found that reserved rights to an aquatic resource also encompass subsidiary rights to support the resource.[58] These commenters opined that those decisions do not stand for the proposition that a resource reserved pursuant to a treaty, statute, or Executive order demands a certain level of water quality. The EPA disagrees with these comments because they misconstrue the role of this framework rule and the relevant inquiry into Tribal reserved rights, as used in this rule.[59]

Consideration of whether Tribal treaty, statutory or Executive order-based rights are applicable turns in part on whether they reserved a right to aquatic and/or aquatic-dependent resources that are protected under the CWA. If they do, and they are asserted by right holders, then the requirements in this rule would apply such that consideration of those rights would be part of the standard-setting process under CWA section 303(c). Their consideration in that process, however, does not hinge on whether the relevant treaty, statute, or Executive order, explicitly references water quality or has been interpreted to imply a right to a certain level of water quality. The requirements set forth in this final rule are not premised on any one treaty, statute, or Executive order, and, accordingly, the rule's substantive water quality requirements set forth in 40 CFR 131.9 do not stem from any potential water quality subsidiary rights in any one treaty, statute, or Executive order. Rather, the rule's requirements are premised on the EPA's recognition of the multitude of Federal treaties, statutes, and Executive orders that reflect various reserved rights to aquatic and aquatic-dependent resources held by Tribes. Whether, and how, a particular reserved right applies will be determined on a case-by-case basis given the facts and the relevant Federal treaties, statutes, and Executive orders.

For purposes of this rule's application in a specific context, the relevant question is not whether a treaty, statute, or Executive order is properly interpreted to reserve a subsidiary right to a particular level of water quality, but rather, whether such an instrument is properly interpreted to reserve a right to an aquatic or aquatic-dependent resource. For example, does a treaty reserve a right to fish? If so, this rule's requirements are aimed at ensuring that where Tribes wish to bring such rights to the state's attention, the state will consider the Tribe's assertion of the right in following the well-established standard setting process pursuant to the EPA's CWA section 303(c) implementing regulation at 40 CFR part 131. In that context, where supported by available data and information, the state will take into consideration whether water quality is sufficient to protect that aquatic resource and right holders exercising their right to that resource. In this final rule, the agency is revising its implementing regulation to set forth a transparent framework to ensure that such aquatic resource rights are protected under the CWA.

Some commenters also asserted that the then-pending Supreme Court case, *Arizona* v. *Navajo Nation,* is relevant to this rule and/or that the United States' position in that case was inconsistent with the EPA's position in the proposed rulemaking. The issue in that case was whether the United States has an affirmative, judicially enforceable fiduciary duty to assess and address the Navajo Nation's need for water from particular sources. The Navajo Nation argued, in pertinent part, that implied rights to water quantity pursuant to *Winters* v. *United States,* 207 U.S. 564, 576–577 (1908), created such an affirmative fiduciary trust duty. The United States argued that prior Supreme Court decisions made clear that a Tribe cannot sue to enforce an asserted fiduciary trust obligation against the United States unless the Tribe can ''identify a specific, applicable, trust-creating statute or regulation that the Government violated.'' [60] The Supreme Court issued its opinion on June 22, 2023, holding that, consistent with the United States' position, while pursuant to the *Winters* doctrine the Tribe held treaty-reserved water quantity rights, those rights ''did not require the United States to take affirmative steps to secure water for the Tribe.'' [61]

Nothing in this rule conflicts with or is contrary to that position. As explained above, the EPA's authority for this rule is the CWA. The EPA is not issuing this rule pursuant to any specific, trust-creating language in any treaty, statute, or Executive order. Rather, it is issuing this rule to ensure that, in implementing the CWA's WQS requirements, the EPA and states are adequately considering rights reserved by treaty, statute or Executive order in establishing WQS for waters where Tribal reserved rights, as defined in this rule, apply. As further explained below, this rule also does not apply to rights to specific quantities of water nor address the quantification of *Winters* rights. Rather, this rule applies to rights to aquatic or aquatic-dependent resources that are protected under the CWA. Accordingly, the EPA disagrees with comments asserting that the *Navajo Nation* case is relevant here.

3. Basis for Amending the Existing WQS Regulations

The EPA established the core of the WQS regulation in a final rule issued in 1983. Since that time, the agency has modified 40 CFR part 131 three times.[62] The agency has explained that such updates have been in response to challenges that ''necessitate a more effective, flexible and practicable approach for the implementation of WQS and protecting water quality,'' and that such updates are informed by the extensive experience with WQS implementation by states, authorized Tribes, and the EPA.[63]

As described above in section III.B.2 of this preamble, in the absence of explicit regulatory requirements aimed at ensuring protection of Tribal reserved rights, the EPA has previously addressed Tribal reserved rights case-by-case in exercising its oversight authority in reviewing state-adopted WQS. Notably, when the EPA promulgated the WQS regulation at 40 CFR part 131 in 1983, the agency considered adding regulatory requirements to ensure that state WQS complied with applicable international treaties. Specifically, in the 1983 final

[58] One commenter also cited to case law in which a court held that a treaty right to fish did not equate to ''an absolute right to the preservation of the fish runs in their original 1855 [treaty] condition, free from all environmental damage caused by the migration of increasing numbers of settlers and the resulting development of land.'' *Nez Perce* v. *Idaho Power,* 847 F. Supp. 791, 808 (D. Id. 1994).

[59] In response to comments on a 2020 decision reversing aspects of the EPA's 2015 Maine WQS disapproval, the EPA expressed a similar view to these commenters. There, the EPA asserted that it was ''unnecessary'' to ensure protection of applicable statutorily reserved rights because the Indian land claims settlement statutes at issue did not ''themselves . . . address or reference designated uses, water quality criteria, or the desired condition or use goal of the waters covered by the sustenance fishing provisions.'' As explained herein, the EPA has clarified that whether the relevant treaty, statute, or Executive order explicitly references water quality or has been interpreted to imply a right to a certain level of water quality is not relevant to applying this rule.

[60] Petition for Certiorari, *United States* v. *Navajo Nation,* Dkt. No. 22–51 at 14 (U.S. July 15, 2022) (citing *United States* v. *Jicarilla Apache Nation,* 564 U.S. 162, 177 (2011)). The United States' petition was granted and consolidated with a petition filed by the State of Arizona. Dkt. No. 21–1484.

[61] *Arizona* v. *Navajo Nation,* 599 U.S. 555, 564 (2023).

[62] *See Water Quality Standards Regulatory Revisions,* 80 FR 51020, 51021 (August 21, 2015) (Describing the history of the EPA's regulation at 40 CFR part 131).

[63] *Id.*

rule establishing the WQS regulation, the agency noted that it had received comments asserting that the EPA should ''require States to adopt standards that meet treaty requirements.'' [64] In response, the agency explained that such issues ''have been adequately resolved previously without the need for regulatory language,'' and, accordingly, that the ''EPA sees no need to include such language in the Final Rule.'' [65] The agency further reasoned that ''[a]ny specific treaty requirements have the force of law,'' and therefore, ''State water quality standards will have to meet any treaty requirements.'' [66]

With respect to Tribal treaties, part of the rationale that the EPA articulated in the 1983 final rule applies equally here: like international treaties, Tribal treaty requirements have the force of law, and thus, in the context of the CWA where WQS must protect the public health or welfare and enhance the quality of water, state WQS must be consistent with any applicable treaty requirements. However, the other element of the agency's asserted reasoning for not adding explicit requirements regarding international treaties has less application here. Namely, while issues regarding WQS and international treaties had been ''resolved previously without the need for regulatory language,'' such resolution—while it has occurred—has been more challenging with respect to issues with WQS and Tribal treaties.[67] As detailed above, in practice the application of specific Tribal reserved rights in the WQS context has lacked consistency and transparent national expectations. The agency's prior incorporation of rights reserved to Tribes by treaty or other sources of Federal law in the WQS context was premised on harmonizing the relevant treaties or statutes with existing CWA requirements, and included interpreting Maine, Washington, and Idaho's fishing designated uses, which those states opposed.[68] That opposition was in part based on those states' views of their own uses, as well as what those states perceived as a new approach to WQS that was taken without notice and comment.[69] The explicit regulatory requirements contained in this final rule, which the agency is promulgating after receiving input from states, Tribes, and other commenters, are thus necessary to establish a set of consistent procedures, expectations, and definitions.

IV. Overview of This Final Rule

A. Definitions and Scope

This final rule provides new regulatory definitions of ''Tribal reserved rights'' and ''right holders'' at 40 CFR 131.3. This rule defines Tribal reserved rights, for purposes of 40 CFR part 131, as ''any rights to CWA-protected aquatic and/or aquatic-dependent resources reserved by right holders, either expressly or implicitly, through Federal treaties, statutes, or executive orders.'' Similarly, for purposes of 40 CFR part 131, this final rule defines ''right holders'' as ''any Federally recognized Tribes holding Tribal reserved rights, regardless of whether the Tribe exercises authority over a Federal Indian reservation.'' The scope of resources covered by this final rule is reflected in the definition of ''Tribal reserved rights,'' which refers to ''rights to CWA-protected aquatic and/or aquatic-dependent resources.''

1. Changes to Proposed Definitions

The final definitions differ from the proposed definitions in three ways, based on public input. First, the EPA added ''for purposes of this part,'' to both the definitions of ''Tribal reserved rights'' and ''right holders,'' simplified the definition of ''right holders'' to reference the definition of ''Tribal reserved rights'' to reduce redundancy, and added ''CWA-protected'' to the definition of ''Tribal reserved rights.'' Second, the EPA revised both definitions to address comments about potential confusion with the definition of ''Indian Tribe or Tribe'' at 40 CFR 131.3(l). Third, in the definition of ''Tribal reserved rights'' the EPA added ''Federal'' before ''treaties, statutes, or executive orders'' and deleted ''or other sources of Federal law.'' These changes from proposal are discussed, in turn, below.

The first set of revisions the EPA made to the proposed definitions at 40 CFR 131.3 was to add ''for purposes of this part,'' to both the definitions of ''Tribal reserved rights'' and ''right holders'' to clarify that both new definitions are applicable only for purposes of the EPA's 40 CFR part 131 regulation. The EPA made this change in response to some commenters who requested that the EPA revise the definition of ''Tribal reserved rights'' to clarify that the way Tribal reserved rights are considered in the WQS context does not dictate or limit how those rights could be considered in other contexts. Similarly, the EPA's addition of the phrase ''CWA-protected'' in the definition of ''Tribal reserved rights'' clarifies that for purposes of this rule the EPA is establishing that definition pursuant to its CWA authority, for consideration in the WQS context. This also does not dictate or limit how treaty, statutory or Executive order-based reserved rights may be considered in other contexts. In response to comments noting that the proposed definition of ''right holders'' was redundant because it repeated the definition of ''Tribal reserved rights'' from 40 CFR 131.3(r), the EPA replaced ''holding rights to aquatic and/or aquatic dependent resources pursuant to . . .'' with ''holding Tribal reserved rights.''

The second change the EPA made to the proposed definitions at 40 CFR 131.3 is intended to clarify that the definition of ''Indian Tribe or Tribe'' at 40 CFR 131.3(l) is not implicated in the definitions of either ''Tribal reserved rights'' or ''right holders.'' Some commenters noted that the definition of ''Indian Tribe or Tribe'' at 40 CFR 131.3(l) is limited to federally recognized Tribes ''exercising governmental authority over a Federal Indian reservation.'' This definition mirrors the definition in CWA section 518(h), which defines ''Indian Tribe or Tribe'' as ''any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal

[64] *Water Quality Standards Regulation.* 48 FR 51400, 51412 (November 8, 1983).

[65] *Id.*

[66] *Id.* at 51413.

[67] The EPA previously took the position that the best way to ensure that risk levels and criteria protect Tribal reserved rights is in reviewing WQS submissions. In response to comments on the EPA's 1998 draft Human Health Methodology revisions, the agency asserted: ''As stated in the 1998 draft Methodology revisions, 'risk levels and criteria need to be protective of tribal rights under Federal law (*e.g.,* fishing, hunting, or gathering rights) that are related to water quality.' We believe the best way to ensure that Tribal treaty and other rights under Federal law are met, consistent with the Federal trust responsibility, is to address these issues at the time EPA reviews water quality standards submissions.'' (*See* 65 FR 66444, 66457 (November 3, 2000)). As explained herein, the EPA has revisited the latter position based on its subsequent application of these principles and is now finalizing these regulations to establish transparent national expectations with respect to WQS and Tribal rights.

[68] *See* Plaintiff's Motion for Judgment on the Administrative Record, *Maine* v. *Pruitt,* No. 1:14–cv–00264–JDL. Dkt. No. 119 at 19 (D. Me. 2018) (Asserting that the EPA's interpretation of Maine's fishing use, with which the State disagreed, and related requirements to protect that use were ''never subjected to any public notice, comment or other process.''); Amicus Curiae the State of Idaho's Brief in Support of Plaintiffs, *Maine* v. *Pruitt,* No. 1:14–cv–00264–JDL, Dkt. No. 126 at 9 (D. Me. 2018).

[69] *See id.; see also* Northwest Pulp & Paper Association, et al., Petition for Reconsideration of EPA's Partial Disapproval of Washington's Human Health Water Quality Criteria and Implementation Tools submitted by the State of Washington on August 1, 2016, and Repeal of the Final Rule Revision of Certain Federal Water Quality Standards Applicable to Washington (February 21, 2017).

Indian reservation.'' This definition is expressly limited to CWA section 518, the provision of the statute in which Congress authorized the EPA to treat an Indian Tribe as a state for purposes of enumerated CWA programs for waters ''within the borders of an Indian reservation.''

The EPA's authority for these new regulatory requirements is distinct from the treatment as a state authority granted in CWA section 518. Accordingly, to avoid any confusion regarding the CWA section 518-based definition of ''Indian Tribe or Tribe'' at 40 CFR 131.3(l), the EPA replaced the phrase ''reserved or held by Tribes'' in the definition of ''Tribal reserved rights'' with ''reserved by right holders.'' This change is intended to streamline the text and provide clarification and does not alter the scope of the rights covered.

For the same reasons, the EPA also added language to the definition of ''right holders'' to clarify that the limitation included in the definition of ''Indian Tribe or Tribe'' at 40 CFR 131.3(l) to Tribes ''exercising governmental authority over a Federal Indian reservation'' does not apply to this definition. Namely, ''right holders'' are defined to include ''any Federally recognized Tribes holding Tribal reserved rights, regardless of whether the Tribe exercises authority over a Federal Indian reservation.'' This additional language is intended to clarify that, for purposes of this rule, ''right holders'' can include federally recognized Tribes that are outside the scope of the definition at 40 CFR 131.3(l).

Lastly, for both the definition of ''Tribal reserved rights'' and the definition of ''right holders,'' the EPA added the word ''Federal'' before ''treaties, statutes, or executive orders'' and deleted ''or other sources of Federal law.'' The EPA added the word ''Federal'' to clarify that, for purposes of this rule, the rights at issue are those reserved through Federal law. Some commenters requested that the EPA broaden the scope of legal instruments in the definition of ''Tribal reserved rights'' to encompass rights that are not reflected in Federal law, such as rights pursuant to state law and rights specified in treaties that were never ratified by the U.S. government. The EPA is maintaining the intent of the proposed rulemaking, which defined reserved rights as those reserved through Federal law. This is consistent with the agency's approach to ensure its actions—including its approval and disapproval actions under CWA section 303(c)(3) and its promulgation of final rules under CWA section 303(c)(4)—are consistent with Federal treaties, statutes, and Executive orders memorializing the rights of federally recognized Tribes.

Regarding the deletion of ''or other sources of Federal law,'' some commenters noted that this term was vague. The EPA initially included this term to capture the full universe of Federal legal rights. However, after consideration of comments, the EPA concluded that the definition sufficiently captures all relevant rights without this additional language.

2. Scope of Resources Covered

This final rule, consistent with the proposed rulemaking, provides at 40 CFR 131.3 that ''Tribal reserved rights'' for purposes of 40 CFR part 131 are ''any rights to CWA-protected aquatic and/or aquatic-dependent resources . . .'' In the preamble to the proposed rulemaking, the EPA noted that examples of resources to which Tribes may have reserved rights ''include but are not limited to the rights to fish; gather aquatic plants; and to hunt for aquatic-dependent animals,'' and the agency requested comment on whether there are additional types of rights reserved to Tribes by treaty, statute, or Executive order that it should consider that were not included in the rule's proposed text.[70] The EPA received many comments on this point.[71] A few commenters supported the scope of resources covered under the definition in the proposed rulemaking, asserting that it is not necessary or appropriate to enumerate all the possible resources to which Tribes could hold reserved rights. Most commenters took the opposite view and requested that the EPA delineate the scope of resources or waters potentially covered by the rule. About half of these asserted that the definition of Tribal reserved rights is overbroad and should be narrowed, while the other half requested that the EPA explicitly expand the definition of Tribal reserved rights to ensure that the rule covers additional resources. After careful consideration, and for the reasons explained herein, the agency decided to maintain the regulatory language as proposed and not to enumerate potentially covered rights in the definition of ''Tribal reserved rights'' or otherwise expand or narrow the definition. The definition of ''Tribal reserved rights'' in this final rule is intended to capture the full spectrum of rights to aquatic and aquatic-dependent resources that are covered by the CWA and thus could be addressed by WQS. The key inquiry in determining whether a right is ''to [a] CWA-protected aquatic and/or aquatic-dependent resource[ ]'' for purposes of this rule is whether the right falls within the ambit of the resources protected under the CWA. CWA section 303(c)(2)(A) states that WQS ''shall be such as to protect the public health or welfare, enhance the quality of water and serve the purposes of this Act.'' ''Serve the purposes of this Act,'' as defined in CWA sections 101(a)(2) and 303(c), means that WQS should, wherever attainable, provide water quality ''for the protection and propagation of fish, shellfish and wildlife and for recreation in and on the water'' and take into consideration the use and value of public water supplies, propagation of fish, shellfish, and wildlife, recreation in and on the water, and agricultural, industrial, and other purposes including navigation. Consistent with CWA sections 101(a)(2) and 303(c)(2)(A), 40 CFR 131.2 provides that ''states adopt water quality standards to protect public health or welfare, enhance the quality of water and serve the purposes of the Clean Water Act (the Act).'' Accordingly, any aquatic or aquatic-dependent resources or practices to which Tribes have reserved rights that fall within that ambit may be relevant Tribal reserved rights for purposes of this rule. The EPA is available upon request to assist right holders and states in assessing the relevance of rights to aquatic or aquatic-dependent resources for purposes of this rule.

3. Scope Related to Allocation or Quantification of Water Rights

Under the Supreme Court's longstanding reserved water rights doctrine, sometimes referred to as the *Winters* doctrine, the reservation of land for an Indian Tribe (or other Federal purposes) ''also implicitly reserves the right to use needed water from various sources—such as groundwater, rivers, streams, lakes, and springs—that arise on, border, cross, underlie, or are encompassed within the reservation.'' [72] In the proposed rulemaking, the EPA noted ''Tribal reserved rights as defined in this proposed rule generally do not

[70] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74367 (December 5, 2022).

[71] Commenters provided many examples of reserved resources and practices, including terrestrial species, medicinal plants, shellfish, hunting and trapping of waterfowl and mammals, commercial harvest and international trade of resources, as well as the right to pray and/or conduct traditional ceremonial practices such as weaving and sweat lodge ceremonies in which Tribal members utilize and come into direct contact with water.

[72] *Arizona* v. *Navajo Nation,* 599 U.S. at 561.

address the quantification of *Winters* rights.'' [73] The EPA received some comments addressing that statement, as well as the perceived implications of the proposed rulemaking on *Winters* rights allocations and water quantity allocations generally. Almost all of these commenters requested that this rule explicitly include or exclude federally reserved water rights. Many of these commenters expressed concern that the proposed rulemaking had the potential to complicate or improperly interfere with the quantification of water rights.

The EPA disagrees with commenters asserting that regulatory text is necessary to address *Winters* rights and other water rights and disagrees with comments asserting that this rule will complicate or interfere with new or existing water rights allocations or quantifications. Congress explicitly addressed the intersection between the CWA and water quantity allocations in CWA section 101(g), providing that ''the authority of each State to allocate quantities of water within its jurisdiction shall not be superseded, abrogated, or otherwise impaired'' by the Act, and that nothing in the CWA ''shall be construed to supersede or abrogate rights to quantities of water which have been established by any State.'' Relatedly, in CWA section 518(a) Congress clarified that ''Indian Tribes shall be treated as States for purposes of such section 101(g).'' Nothing in this rule conflicts with these statutory provisions, or the EPA's WQS regulations at 40 CFR 131.4(a) (''[W]ater quality standards shall not be construed to supersede or abrogate rights to quantities of water.''). Nothing in this rule affects a state's or Tribe's authority to allocate water quantities nor provides a basis to supersede or abrogate rights to quantities of water.[74] In accordance with these provisions of the CWA and the EPA's implementing regulations, whether a Tribe has right to a quantity of the water itself is not relevant to the application of this rule, which sets forth requirements for states in establishing WQS where Tribes assert rights to CWA-protected aquatic or aquatic-dependent resources.

The EPA is also clarifying its statement in the preamble of the proposed rulemaking that ''Tribal reserved rights generally do not address the quantification of *Winters* rights.'' [75] The EPA's inclusion of the term ''generally'' in the proposed rulemaking preamble, which created confusion, was solely to recognize that, consistent with other WQS actions, water quantity would come into play only to the extent that a certain quantity or flow was under consideration in WQS development to protect an aquatic or aquatic-dependent resource. For example, that a Tribe may have a right to a certain number of acre feet of water is itself not relevant in establishing WQS. In contrast, if a Tribe has a right to fish and provides data that a certain flow rate is necessary for fish survival, that would be potentially relevant under this rule. In that scenario, considerations regarding quantity or flow would not be based on *Winters* rights, but rather would be focused on protecting a relevant designated use. Accordingly, any effects of this rule on water rights, including *Winters* rights, would be incidental to water quality goals.[76]

B. Protecting Applicable Tribal Reserved Rights

Section 131.9(a) of this final rule adds several requirements to the EPA's existing WQS regulation that apply where a right holder asserts a Tribal reserved right in writing to a state and the EPA for consideration in establishment of WQS. In such circumstances, the state must, to the extent supported by available data and information: (1) take into consideration the use and value of its waters for protecting the Tribal reserved right in adopting or revising designated uses; (2) take into consideration the anticipated future exercise of the Tribal reserved right unsuppressed by water quality in establishing relevant WQS; and (3) establish water quality criteria to protect the Tribal reserved right where the state has adopted designated uses that either expressly incorporate protection of the Tribal reserved right or encompass the right. This latter requirement includes, for human health criteria, developing criteria to protect right holders using at least the same risk level (*e.g.,* cancer risk level, hazard quotient, or illness rate) as the state would otherwise use to develop criteria to protect the state's general population (*i.e.,* non-right holders), paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right. Each of these requirements is discussed in turn in section IV.B.1 through IV.B.3 of this preamble, along with an explanation of the changes that the EPA made to the proposed requirements in response to public comments, to improve clarity and implementation of this final rule.

Pursuant to the language in 40 CFR 131.9(a), this rule's requirements are triggered when right holders assert their reserved rights to CWA-protected aquatic and aquatic-dependent resources for consideration in the establishment of WQS. The EPA recognizes that treaties, statutes, and Executive orders constitute binding legal requirements regardless of whether a right holder chooses to assert rights reserved by such instruments in the context of the CWA WQS program. A right holder's decision to raise such reserved rights for consideration in establishing WQS is based on the specific nature of that right and the specific WQS in question. For example, a right holder may have a treaty-reserved right to fish but choose not to assert or raise that right in the context of a state's planned revision to its human health criteria. The right holders' calculus in whether to assert a right entails numerous considerations, such as whether the WQS revisions at issue are focused on pollutants that impact the right holders' ability to exercise their right. If not, and the right holder decides not to raise their right to the state and the EPA, that decision in no way alters the legal scope or meaning of that right. Accordingly, a decision not to raise a right in a specific WQS context does not amount to a general waiver or disclaimer of that right in the WQS context or in other contexts, including with respect to other state or Federal actions that may impact Tribal reserved rights. Additionally, a decision not to raise a right during a specific state WQS development process does not

[73] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74363 (December 5, 2022).

[74] *Winters* rights arise by implication, vest no later than the establishment or creation date of the Indian or non-Indian Federal reservation and may be quantified through a Congressionally enacted settlement or through adjudication in Federal or state court consistent with the McCarran Amendment. *See, e.g., Colorado River Water Conserv. Dist.* v. *United States,* 424 U.S. 800, 808–09 (1976); *Arizona* v. *California,* 373 U.S. 546, 595–601 (1963); *United States* v. *Adair,* 723 F.2d 1394, 1413–14 (9th Cir. 1983), cert. denied, 467 U.S. 1252 (1984).

[75] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74363 (December 5, 2022).

[76] *See Public Utility District No. 1 of Jefferson County et al.* v. *Washington Department of Ecology,* 511 US 700, 720 (1994) (''Sections 101(g) and 510(2) preserve the authority of each State to allocate water quantity as between users; they do not limit the scope of water pollution controls that may be imposed on users who have obtained, pursuant to state law, a water allocation.''); citing to the Legislative History of the Clean Water Act of 1977 (''The requirements [of the Act] may incidentally affect individual water rights . . . . It is not the purpose of this amendment to prohibit those incidental effects. It is the purpose of this amendment to insure that State allocation systems are not subverted, and that effects on individual rights, if any, are prompted by legitimate and necessary water quality considerations.'').

preclude the right holder from raising that reserved right during another WQS development process.

The rule's requirements are premised on a right holder asserting a right to a state and the EPA ''for consideration in establishment of [WQS],'' and accordingly, an assertion that occurs after the state has established its WQS would not trigger the rule's requirement that the state consider that right, at that time, but would be relevant for future WQS revisions. Assertions that occur as early as possible in a state's WQS development process will help to ensure adequate time for all parties to resolve any uncertainties and consider whether and how WQS may need to be revised in accordance with 40 CFR 131.9(a). Additionally, asserting the rights and providing associated details early in the WQS development process ensures that the state can consider that information before it has invested significant resources in drafting new or revised WQS, and before those new or revised WQS have been duly adopted.[77] The CWA requires states to conduct a triennial review of their WQS and solicit public input on changes that may be needed to those WQS. In the absence of a separate state process for engaging potential right holders, the state's triennial review process is an ideal opportunity for Tribes to assert their rights for consideration.

The EPA does not intend for the requirement for right holders to assert their rights to a state and the EPA in writing for consideration in establishment of WQS to be onerous. For example, an email with information about the rights would suffice. When right holders choose to assert their rights in the WQS context, the EPA encourages right holders to provide as much detail and documentation as possible on the geographic scope and nature of the rights (*e.g.,* the right to fish for subsistence in geographic area Y; the right to gather plants in waterbody A).

If a right holder asserts a right in the WQS context, then the next step is for the state to seek further information from the right holder and other sources, if needed, to help the state determine the nature and geographic scope of the right, and whether and how state WQS may need to be revised in accordance with 40 CFR 131.9.[78] Accordingly, the EPA also encourages right holders to provide data and information, where available, about desired revisions to relevant WQS. It may be useful for the state to initiate a collaborative process with the EPA and the right holder so all parties receive the same information and can jointly discuss any areas of uncertainty. In the proposed rulemaking, the EPA explained that ''a first step'' in determining the rule's applicability ''should be engagement with potential right holders.'' [79] Accordingly, the EPA proposed adding § 131.6(g)(1), which would have required that WQS submissions include ''[i]nformation about the scope, nature, and current and past use of the [T]ribal reserved rights, *as informed by the right holders*'' (emphasis added).[80] The intent of this provision was to ensure that the identification and interpretation of any relevant Tribal reserved rights would be informed by input from the right holders.[81] Some commenters expressed confusion regarding what the EPA meant by ''as informed by the right holders,'' and what the respective roles of states, the EPA, and right holders would be in initially determining whether there are relevant rights to consider. Accordingly, the EPA revised 40 CFR 131.9(a) to clarify that §§ 131.9(a)(1) through (3) only apply where ''a right holder has asserted a Tribal reserved right in writing to the State and EPA for consideration in establishment of [WQS].'' The EPA also revised the proposed language at 40 CFR 131.6, discussed further below.

This revision to 40 CFR 131.9(a) serves two important purposes. First, in response to concerns raised by some commenters regarding states or the EPA interpreting and applying rights reserved to Tribes pursuant to treaties, statutes or Executive orders in ways that are contrary to right holders' characterizations of their rights, it allows right holders to decide whether to raise their rights for consideration in the WQS context and provide relevant information about those rights. The EPA is available to assist right holders in understanding state WQS development processes to help them determine when they may wish to assert relevant rights in the WQS context. For example, the EPA can direct right holders to information on state WQS development processes so they can stay informed, such as through participation in workgroups and signing up for state email distribution lists on WQS topics.[82]

Second, this revision provides states with requested clarity regarding the scope of rights that they need to consider in the WQS context, *i.e.,* those rights asserted by right holders. The EPA received some comments expressing concerns regarding implementation of the rule and the potential burden placed on states if they had to independently identify all applicable Tribal reserved rights in their waters before proceeding with WQS revisions. This change clarifies that such an identification is not required to comply with this rule. However, the EPA recommends that states engage with Tribes at the earliest stages of their WQS development processes to gain additional knowledge regarding any potentially applicable reserved rights and related WQS concerns before right holders assert those rights. The EPA understands from public comments that some states are already aware of potentially applicable reserved rights and routinely engage with right holders on WQS and other actions that may impact those rights; the EPA encourages that practice. By proactively providing opportunities for Tribes to engage in the WQS development process (for example, by notifying all federally recognized Tribes in the early stages of a triennial review that the Tribes may be affected by amendments to a state's WQS), states can best position right holders to make informed decisions about whether to assert their reserved rights at a stage when the state has the most flexibility to consider new information and use that information to develop revised WQS, as appropriate. The EPA is also available to assist states in identifying potential right holders.

Some commenters requested that the EPA and states keep confidential certain information about Tribal reserved rights, such as culturally sensitive information on water uses. Where a Tribe has concerns about sensitivity of

[77] Tribal assertions of reserved rights to the EPA and the relevant state(s) do not necessarily need to occur solely as part of the WQS development process but can be part of any other process addressing expressed Tribal interests, as long as the assertion relates specifically to WQS.

[78] The EPA notes that a right holder asserting a right does not necessarily mean that application of 40 CFR 131.9 will lead to a WQS revision in that instance.

[79] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74367 (December 5, 2022).

[80] *Id.*

[81] In its slides for the public hearings on the proposed rulemaking, the EPA stated, ''Whether reserved rights apply to waters subject to a specific new/revised WQS is a complex inquiry that will be informed by several factors, including: input from the right holders; language of the treaties, statutes, or Executive orders and relevant judicial precedent.'' *See https://www.epa.gov/system/files/documents/2023-02/01-24-23-Reserved-Rights-Public-Hearing-Slides-508.pdf.*

[82] The EPA has included in the docket for this rule an example implementation scenario illustrating the types of information that could constitute an assertion of rights for consideration in establishment of WQS, as well as the process steps leading from an assertion of rights to state adoption of new or revised WQS and the EPA's approval or disapproval. The EPA expects to further work with Tribes and states in the implementation of this rule.

information, in advance of sharing that information, the EPA and the Tribe should discuss the extent to which the information would likely influence the WQS revision process and steps that could be taken to protect confidentiality. The EPA and states are unlikely to be able to keep most information provided by Tribes confidential, for two reasons. First, to have any bearing on a WQS action, a right holder's assertion of a right would need to be part of the public record for any related WQS action. CWA section 101(e) provides that ''public participation in the development, revision, and enforcement of any regulations, standard, effluent limitation, plan, or program established . . . under this Act shall be provided for, encouraged, and assisted . . .'' In addition, the EPA's regulation related to public participation in the development of WQS, 40 CFR 131.20(b), references 40 CFR part 25, which requires states to provide ''[r]eports, documents and data'' relevant to discussion of proposed WQS revisions in advance of public hearings on such revisions. Information relevant to the proposed WQS and their relationship to Tribal reserved rights would therefore be subject to public review and comment. Second, the EPA is subject to the Freedom of Information Act (FOIA), and, accordingly, FOIA disclosure requirements would apply to information provided to the EPA by right holders.[83] The EPA is only able to maintain confidentiality of information protected by one of the nine exemptions in the FOIA. FOIA disclosure requirements would likely apply to most information provided to the EPA by right holders in the context of this rule.

The requirements in 40 CFR 131.9(a) are premised on states having ''available data and information'' supporting the application of those requirements. As explained above in this section of this preamble, once a right holder asserts a right, the state would seek available data and information, with assistance from the EPA if requested, and then evaluate the data and information to determine whether and how WQS may need to be revised to comply with 40 CFR 131.9(a). The EPA and the state will need to make their decisions based on the information available at the time of the WQS revision. Where a right holder asserts a right but only limited data and information about the nature and scope of the right, or the level of protection required to protect the relevant resource, can be found at the appropriate stage in the state's WQS development process (for example, before a state has duly adopted its WQS and/or the WQS are before the EPA for review under CWA section 303(c)), it could be reasonable to conclude that the information was not ''available'' per § 131.9(a) when the WQS were being developed. The triennial review process exists to ensure that any new information that was not previously addressed is considered and incorporated in a future WQS revision, as appropriate. In such cases, the state, the right holder, and the EPA should discuss next steps for a future WQS revision to address the new information, as needed, as well as how the right could be protected until that future WQS revision occurs (*e.g.,* through implementation of a narrative criterion).

A few commenters raised concerns about the complexity for right holders with rights that span multiple states of needing to engage with different states on different WQS revision timelines and with different strategies for protecting Tribal reserved rights. In such situations, if requested by one or more states or Tribes, the EPA is available to engage with multiple states and right holders to negotiate regional solutions.

Some commenters stated that the phrase ''to the extent supported by available data and information'' needed additional clarification on the appropriate data that would satisfy this requirement. The quality and soundness of available data and information will need to be evaluated case-by-case during the WQS development process. As is currently the case in development of WQS under the EPA's existing regulation at 40 CFR part 131, different parties sometimes have different opinions on the types of data to consider, and the quality and soundness of those data. The EPA received some comments expressing concern that there would be disputes between states and Tribes on appropriate methodologies and/or scientific data and information, and that there is the potential for additional workload burden to resolve these disputes or produce data and information. As stated in 40 CFR 131.9(b), ''States and right holders may request EPA assistance with evaluating Tribal reserved rights''—which could include gathering or producing data and information—and ''EPA will provide such assistance to the extent practicable.'' As for any WQS decision, states must evaluate all the available information and make their decisions based on that information. As explained below in section IV.E, the EPA will review all of the available information and the state's documentation of how that information was considered per 40 CFR 131.6(g) and decide whether to approve or disapprove a state WQS submission in the same way the EPA currently makes decisions when there are disagreements between different parties, including different states, on WQS protections.

The EPA requested comment on whether there are other factors it should consider when making WQS decisions where there are gaps in information, and/or a difference of opinion exists between the state and one or more Tribes about the level of water quality necessary to protect a reserved right. A few commenters asserted that relevant Traditional Ecological Knowledge, also referred to as Indigenous Knowledge, should be considered along with other types of data and information; the EPA agrees.

Some commenters noted that right holders may need resources and support from the EPA to collect data and information. The EPA intends to provide support to right holders, as well as states, during the WQS development process to help gather available data and evaluate differing scientific views to meet the requirements in this final rule. The EPA has, on occasion, provided funding to collect data and information to inform the level of water quality necessary to support Tribal reserved rights. The EPA could support similar projects in the future, as appropriate and as funding allows.

In the proposed rulemaking, 40 CFR 131.9(a) provided that ''[w]ater quality standards must protect [T]ribal reserved rights applicable to waters subject to such standards.'' [84] In response to comments expressing confusion about the meaning and application of this language, in this final rule, the EPA removed the initial overarching statement of principle proposed at 40 CFR 131.9(a), which the agency did not intend as a stand-alone requirement.

Finally, some commenters requested that the EPA amend proposed 40 CFR 131.9(a) to specify that upstream WQS must protect downstream Tribal reserved rights. The EPA made no changes to the final rule in response to these comments because, pursuant to the existing WQS regulation at 40 CFR 131.10(b), upstream states are already obligated to ensure that their WQS provide for the attainment and maintenance of downstream state WQS, including WQS that protect Tribal

[83] *See https://www.epa.gov/foia/learn-about-foia.*

[84] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74378 (December 5, 2022).

reserved rights.[85] Many state WQS already include a broad narrative criterion to protect downstream WQS, for example, or a tailored downstream protection narrative focused on specific waters or pollutants. In practice, where a downstream state's WQS are not yet protective of applicable reserved rights, the EPA would prioritize working with that state and the right holder(s) to gather available data and information and adopt appropriate WQS to protect the rights.

1. Considering Tribal Reserved Rights in Designating Uses

The final rule at 40 CFR 131.9(a)(1) requires states to consider the use and value of their waters for protecting applicable Tribal reserved rights in adopting or revising designated uses pursuant to 40 CFR 131.10. Specifically, it requires that states must ''*[t]ake into consideration* . . . Tribal reserved rights in adopting or revising designated uses[.]'' (Emphasis added). This requirement is consistent with CWA section 303(c)(2)(A), which provides that WQS ''shall be established *taking into consideration their use and value* for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial, and other purposes, and also taking into consideration their use and value for navigation.'' (Emphasis added).

The EPA's existing regulation at 40 CFR 131.6(a) requires that each state's WQS submitted to the EPA for review must include ''[u]se designations consistent with the provisions of [S]ections 101(a)(2) and 303(c)(2) of the Act.'' [86] Some of the uses specified in CWA section 303(c)(2)(A) are also specified in CWA section 101(a)(2), which sets a national goal of ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water,'' wherever attainable. The EPA refers to the uses listed in section 303(c)(2)(A) but not listed in section 101(a)(2) as ''non-101(a)(2) uses.'' [87]

The EPA is not delineating in this final rule a list of uses that states must take into consideration, but notes that the full scope of uses that states are required to consider under the CWA includes those that are explicitly listed in sections 303(c)(2)(A) and 101(a)(2) of the CWA, and those that are not, as evidenced by Congress' inclusion of the phrase ''and other purposes . . .'' in CWA section 303(c)(2)(A). As described in section IV.A.2 of this preamble, commenters provided examples of reserved resources and practices that are captured explicitly in CWA sections 101(a)(2) and 303(c)(2)(A) such as propagation of fish and wildlife, as well as examples that are not captured explicitly in either provision but could fall under section 303(c)(2)(A)'s ''other purposes,'' such as ceremonial practices. As noted above in section III.B.1 of this preamble, rights reserved to Tribes pursuant to treaties, statutes and Executive orders are binding Federal law, and thus, for any such rights that do not already fall within the explicit list of uses set forth in CWA section 101(a)(2) or section 303(c)(2)(A), consideration of waters' use and value for protecting Tribal rights reserved by such legal instruments is encompassed within the ''other purposes'' clause of CWA section 303(c)(2)(A).[88]

In this final rule, where a state finds that certain waters have use and value for protecting a Tribal reserved right based on information provided by right holders that have asserted a relevant right, the state would then consider whether those rights are already encompassed by a state's designated uses, or whether a new or revised use may be needed to protect the Tribal reserved right. 40 CFR 131.10 remains the regulatory framework for guiding this consideration. Many state-designated uses already protect the CWA section 101(a)(2) uses, which likely encompass protection of certain Tribal reserved rights. For example, a state with a ''fishing'' designated use applicable to waters where there is a subsistence fishing reserved right could conclude that its ''fishing'' use encompasses that right such that a new use would not be needed, although the state may still choose to adopt a separate subsistence fishing use for transparency and clarity.

For non-101(a)(2) uses, in the preamble to the EPA's final 2015 revisions to the Federal WQS regulation, the EPA provided several recommendations on the types of information that a state might consider when determining the use and value of its waters for various purposes.[89] In addition to the requirements in 40 CFR 131.10 to provide for the attainment and maintenance of downstream WQS and protect existing uses, the EPA recommended that states consider information such as: (1) the quality and physical characteristics of the water(s) being evaluated, (2) public comments, (3) attainability considerations, and (4) the value and/or benefits (including environmental, social, cultural, and/or economic value/benefits) associated with the use. The EPA also recommended that states work closely with the EPA when developing such ''use and value demonstrations'' for non-101(a)(2) uses in their waters.

In the EPA's view, many waters where Tribal reserved rights apply will have significant environmental, social, cultural and/or economic use and value for protecting those rights in accordance with 40 CFR 131.9. In such cases, the EPA expects that a state would either explicitly adopt a use to protect the Tribal reserved rights or conclude that its current uses encompass the rights. This is because, as emphasized in comments from Tribes, the exercise of rights reserved by Tribes is an intrinsic part of Tribal life and of deep cultural, economic, and subsistence importance to Tribes. For example, where a right holder has a reserved subsistence fishing right on a river, that river would have use and value for protecting subsistence fishing. As such, the state would either explicitly adopt a use to protect subsistence fishing or determine that its current use designation already encompasses subsistence fishing. There may be situations, however, where the use and value of certain waters suggests that designating uses for those waters to protect the reserved right is a higher priority than for other waters where the right applies. For example, natural physical characteristics in one waterbody may inhibit growth or survival of a resource covered by a Tribal reserved right, such that there is little value in designating uses for that

[85] USEPA. 2014. *Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions.* EPA–820–F–14–001. *See https://www.epa.gov/sites/default/files/2018-10/documents/protection-downstream-wqs-faqs.pdf.*

[86] The existing WQS regulation at 40 CFR part 131 interprets and implements CWA section 101(a)(2) and 303(c)(2)(A) through requirements that WQS protect the uses specified in section 101(a)(2) of the Act unless those uses are shown to be unattainable, effectively creating a rebuttable presumption of attainability. This final rule does not alter the existing requirements at § 131.10 that the uses specified in CWA section 101(a)(2) are presumed attainable unless a state affirmatively demonstrates through a Use Attainability Analysis (UAA) that 101(a)(2) uses are not attainable as provided by one of six regulatory factors at 40 CFR 131.10(g). A UAA is defined at 40 CFR 131.3(g) as ''a structured scientific assessment of the factors affecting the attainment of the use which may include physical, chemical, biological, and economic factors as described in § 131.10(g).''

[87] *See* 40 CFR 131.3(q) defining ''non-101(a)(2) uses'' as ''any use unrelated to the protection and propagation of fish, shellfish, wildlife or recreation in or on the water.''

[88] *Grand Portage Band et al.* v. *EPA,* Civil No. 22–1783 (D. Minn. March 29, 2024) at 30 (''States and EPA must consider Tribal treaty rights to aquatic and aquatic-dependent resources to comply with the Clean Water Act and implementing regulations. See 33 U.S.C. 1313(c)(2)–(3), 1371(a); 40 CFR 131.5, 131.6, 131.10(b).'').

[89] *See Water Quality Standards Regulatory Revisions,* 80 FR 51027 (August 21, 2015).

waterbody to specifically protect the reserved right. As with any evaluation of waters' use and value for various purposes, compliance with the requirement at 40 CFR 131.9(a)(1) will require a case-specific evaluation of the waters and circumstances in question. The EPA recommends that states work closely with right holders and with the EPA when undertaking such an analysis.

The final rule reflects two key modifications from the use requirement in the proposed rulemaking, which at 40 CFR 131.9(c)(1) proposed to require states to ''[d]esignate uses . . . that either expressly incorporate protection of the [T]ribal reserved rights or encompass such rights[.]'' [90] First, the EPA aligned the rule's requirement regarding designation of uses with the language of section 303(c)(2)(A) of the CWA by requiring that states must ''[t]ake into consideration . . . Tribal reserved rights in adopting or revising designated uses[.]'' Some commenters viewed the proposed requirement in 40 CFR 131.9(c)(1) that states must ''[d]esignate uses . . .'' as a broad mandate requiring states to adopt designated uses and asserted this was inconsistent with the CWA's framework set forth in section 303(c) and improperly usurped states' roles. The EPA's intent in proposing 40 CFR 131.9(c)(1) was not to impose a new use designation requirement, but rather to make explicit that designating a use to protect rights to aquatic and/or aquatic-dependent resources reserved to Tribes by treaty, statute, or Executive order was one option available to states. It was not intended as a mandate. Given the confusion expressed in comments, the EPA is revising the proposed rulemaking language on designated uses to align with the CWA language.

The second key change the EPA made between proposed 40 CFR 131.9(c) and final 40 CFR 131.9(a)(1) was to remove proposed 40 CFR 131.9(c)(1) through (3), which provided that, in order to meet the requirements of proposed 40 CFR 131.9(a), ''states must'' either: (1) designate uses and (2) establish criteria to protect Tribal reserved rights, ''and/or'' (3) use applicable antidegradation requirements to maintain water quality that protects Tribal reserved rights.[91] As explained immediately above, the final rule includes a revised requirement with respect to designated uses, set forth at 40 CFR 131.9(a)(1). The final rule also includes a revised requirement regarding criteria, related to proposed 40 CFR 131.9(c)(2), that is described below in section IV.B.3 of this preamble. For the reasons explained immediately below, the EPA is not finalizing a requirement related to antidegradation, as set forth at proposed 40 CFR 131.9(c)(3).

The EPA requested comments on whether two proposed antidegradation policy options related to Tier 2 and Tier 3 could be used to protect Tribal reserved rights in lieu of the proposed requirements for designated uses and criteria at 40 CFR 131.9(c)(1) and (2), respectively. Some commenters expressed concerns that, as drafted, the proposed rulemaking implied that applying antidegradation requirements alone could satisfy the statement set forth at proposed 40 CFR 131.9(a) that WQS must protect Tribal reserved rights and expressed confusion about whether the proposed requirement at 40 CFR 131.9(c)(3) differed from the requirements already encompassed in the existing WQS regulation at 40 CFR 131.12. The EPA has determined not to include the proposed provision related to antidegradation because the existing antidegradation requirements can be used to protect reserved rights. Among other requirements, 40 CFR 131.12 specifies that states must develop and adopt a statewide antidegradation policy. As specified in 40 CFR 131.12(a)(2), that policy must require that water quality be maintained and protected for high quality waters unless the state finds that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. This requirement applies to all high quality waters, including those where reserved rights apply. In addition, the existing regulation at 40 CFR 131.12(a)(3) specifies that an antidegradation policy must also provide for the maintenance and protection of water quality where states have determined that such waters constitute an Outstanding National Resource Water (ONRW). Again, this requirement applies to ONRWs where reserved rights apply. In the final rule, the EPA streamlined and clarified the operative requirements set forth in 40 CFR 131.9 by removing the language related to antidegradation. The EPA concluded that existing antidegradation tools specified at 40 CFR 131.12 can be used to protect Tribal reserved rights, therefore the EPA determined it was not necessary to include an additional provision related to antidegradation in 40 CFR 131.9.

The final rule does not change or affect the antidegradation requirements in the EPA's existing WQS regulation at 40 CFR 131.12 or add any new antidegradation regulatory requirements regarding protection of Tribal reserved rights. However, the EPA recommends that states consider applying ONRW protections to maintain and protect waters where Tribal reserved rights apply. The EPA also recommends that states amend their antidegradation implementation methods to explicitly account for Tribal reserved rights when evaluating whether to authorize a lowering of water quality in Tier 2 waters.

2. Accounting for Suppression Effects

In the final rule, 40 CFR 131.9(a)(2) requires that, where a right holder has asserted a Tribal reserved right and where supported by available data and information, the state must ''[t]ake into consideration the anticipated future exercise of the Tribal reserved right unsuppressed by water quality[.]'' This requirement is intended to address situations where existing water quality does not allow for right holders to fully exercise their reserved rights. For example, a Tribe's exercise of its right to fish for subsistence is suppressed if the Tribe consumes fish below subsistence levels due to concerns about contamination. Consideration of suppression effects is important to minimize the potential that WQS merely reinforce an existing suppressed use or allow further contamination and/or depletion of the aquatic resources such that it leads to a ''downward spiral'' of further reduction/suppression.[92]

The EPA proposed to require, at 40 CFR 131.9(a)(1), states to establish WQS to ''protect'' the exercise of Tribal reserved rights ''unsuppressed by water quality or availability of the aquatic or aquatic-dependent resource.'' [93] The requirement related to suppression in the final rule reflects several key modifications to the proposed requirement: first, the EPA made it less prescriptive, while maintaining a requirement that states *consider* the effect suppression is having on the exercise of Tribal reserved rights; second, the EPA clarified the need to evaluate the ''anticipated future'' exercise of Tribal reserved rights

[90] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74378 (December 5, 2022).

[91] *Id.*

[92] National Environmental Justice Advisory Council, *Fish Consumption and Environmental Justice,* pp. 44–49 (2002) (NEJAC Fish Consumption Report) available at *https://www.epa.gov/sites/default/files/2015-02/documents/fish-consump-report_1102.pdf.*

[93] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74378 (December 5, 2022).

unsuppressed by water quality; and third, the EPA removed the reference to availability of the resource.

Requiring consideration of the anticipated future exercise of Tribal reserved rights unsuppressed by water quality is consistent with the objectives of CWA section 303(c)(2)(A), the oversight authority that Congress granted the EPA in CWA section 303(c), and the EPA's existing WQS regulation, and builds on the EPA's longstanding recommendations on derivation of human health criteria. Specifically, requiring states to consider suppression effects in establishing WQS is consistent with the CWA goal in section 101(a) to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters,'' section 303(c)(2)(A)'s requirement that WQS ''shall be such as to protect the public health or welfare'' and ''enhance the quality of the water,'' and the EPA's longstanding position that WQS are water quality goals that are not intended to merely reflect currently attained or existing conditions.[94] As the ''Purpose'' section in the existing WQS regulation at 40 CFR 131.2 explains, WQS ''serve the dual purposes of establishing the water quality goals for a specific water body and serve as the regulatory basis for the establishment of water-quality-based treatment controls and strategies[.]'' Relatedly, the EPA's longstanding regulation at 40 CFR 131.3 defines designated uses as ''those uses specified in water quality standards for each water body or segment *whether or not they are being attained*'' (emphasis added). This definitional language illustrates the principle that WQS may be set based on goals for future water quality, even if such goals are not presently attained.

The requirement at 40 CFR 131.9(a)(2) also builds on the EPA's longstanding guidance addressing derivation of water quality criteria to protect designated uses. For example, in the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000 Methodology), the agency refers to human health criteria as ''health *goals*'' (emphasis added).[95] The EPA's 2016 *Guidance for Conducting Fish Consumption Surveys* recommends avoiding establishing standards based on suppressed conditions and recommends gathering information about anticipated future conditions.[96] In 2013, in a guidance document addressing human health criteria and fish consumption rates, the agency noted the importance of avoiding ''suppression effects'' that may occur when a fish consumption rate ''reflects an artificially diminished level of consumption from an appropriate baseline level of consumption . . . because of a perception that fish are contaminated with pollutants.'' [97]

The requirement in this final rule builds both on the agency's prior guidance on avoiding establishing WQS based on suppressed fish consumption rates, which was not specific to consideration of Tribal reserved rights, as well as on the case-specific actions the agency took in Maine, Washington, and Idaho, discussed previously in section III.B.2 of this preamble, where Tribal reserved rights were a factor in determining the appropriate fish consumption rate. In 2015 and 2016, in disapproving human health criteria for Maine and Washington, respectively, the EPA stated that, where Tribal rights applied, human health criteria must be based on fish consumption data ''that reasonably represent Tribal consumers taking fish from Tribal waters and fishing practices unsuppressed by concerns about the safety of the fish available to them to consume.'' [98] In 2019, the agency revisited the position taken in the Maine and Washington actions, acknowledging the EPA's prior consideration of suppression in evaluating fish consumption rates, but indicating that the concept of requiring a state to use an unsuppressed fish consumption rate based on heritage or historic data was ''new and novel[.]'' [99] The EPA noted that its applicable guidance did not explain how ''historic fish consumption rates are to be used in deriving'' criteria, and indicated that requirements to use heritage or historic data ''should have been presented for thorough public notice and comment prior to being incorporated into the EPA's human health criteria recommendations.'' [100] This final rule is informed by the general principles reflected in the EPA's pre-2019 guidance. In addition, while this final rule does not mandate use of historic or heritage data, in this rule, the EPA expressly addressed any implied procedural deficiency based on the agency's 2019 assertion by requesting public comment on the concepts of requiring protection of unsuppressed exercise of Tribal reserved rights and of using heritage or historic data to evaluate suppression (discussed further in subsequent paragraphs).

Many commenters expressed concerns that a mandate that WQS must protect unsuppressed exercise of a right would be challenging to implement, as determining what constitutes unsuppressed exercise of a Tribal reserved right could be subjective. Many other commenters supported such a mandate to prevent WQS from being established based on suppressed use of a resource. The EPA agrees, as explained above, that it is important to avoid establishing WQS that lock in current levels of contamination. However, based on public input, the EPA is finalizing a requirement that is less prescriptive than proposed and more flexible than the approach the agency took in its Maine and Washington actions. The final requirement does not mandate that states in establishing WQS in waters with applicable Tribal reserved rights,

[94] *See Water Quality Standards Regulatory Revisions,* 80 FR 51020, 51025 (August 21, 2015) (''When conducting a UAA and soliciting input from the public, states and authorized Tribes need to consider not only what is currently attained, but also what is attainable in the future after achievable gains in water quality are realized.'').

[95] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004 at 1–5, *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.*

[96] *See* USEPA. 2016. *Guidance for Conducting Fish Consumption Surveys.* EPA–823B16002 at 18, *https://www.epa.gov/sites/default/files/2016-12/documents/guidance-fish-consumption-surveys.pdf* (''Environmental standards utilizing suppressed rates may contribute to a scenario in which future aquatic environments will support no better than suppressed rates'' and p. 84: ''. . . by asking people to predict their level of future use under the change of a single condition (*e.g.,* alleviation of their concerns about contamination), a survey can provide useful information on the qualitative scale of change that usage rates are likely to undergo as remediation and/or risk communication progresses.'').

[97] *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions. https://www.epa.gov/sites/default/files/2015-12/documents/hh-fish-consumption-faqs.pdf* (''It is also important to avoid any suppression effect that may occur when a fish consumption rate for a given subpopulation reflects an artificially diminished level of consumption from an appropriate baseline level of consumption for that subpopulation because of a perception that fish are contaminated with pollutants.'').

[98] Letter from H. Curtis Spalding, Regional Administrator, EPA Region 1, to Patricia W. Aho, Commissioner, Maine Department of Environmental Protection, ''Re: Review and Decision on Water Quality Standards Revisions'', Attachment A at 3 (February 2, 2015); *see also* Revision of Certain Federal Water Quality Criteria Applicable to Washington, 81 FR 85417, 85424 (November 28, 2016) (''It is also important, where sufficient data are available, to select a FCR that reflects consumption that is not suppressed by concerns about the safety of available fish.'').

[99] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74369 (December 5, 2022), citing to the EPA's Approval of Idaho's New and Revised Human Health Water Quality Criteria for Toxics and Other [WQS] Provisions (April 4, 2019), p. 12.

[100] The EPA's Approval of Idaho's New and Revised Human Health Water Quality Criteria for Toxics and Other [WQS] Provisions (April 4, 2019), p. 12.

''must protect'' the unsuppressed exercise of those rights, nor does it mandate that, with respect to human health criteria, states must categorically use an unsuppressed fish consumption rate in each instance where Tribal reserved fishing rights apply. The final rule instead requires that states must ''take into consideration'' the anticipated future exercise of Tribal reserved rights unsuppressed by water quality. The EPA's existing WQS regulation at 40 CFR 131.11 already requires that WQS protect applicable designated uses and be based on sound science. Protection of applicable designated uses includes analysis of relevant data. Thus, states should already be considering data regarding suppression effects pursuant to the existing WQS regulation and guidance. This final rule underlines the importance of such consideration in the context of protecting Tribal reserved rights.

Consideration of suppression effects pursuant to this final rule will inform states' development of criteria that protect applicable designated uses and are based on sound scientific rationale. In complying with this requirement, states must consider right holders' anticipated future exercise of relevant rights in light of available data and information regarding suppression effects. Consistent with the final rule's requirements at 40 CFR 131.6, states must include in their WQS submittal their analysis of such information and explain how they considered it in revising their WQS. The additional changes that the agency made to this requirement, described below, are aimed at further clarifying what it means to consider suppression effects in establishing WQS.

The next substantive change in the final rule clarifies that states must take into consideration the ''*anticipated future* exercise of the Tribal reserved right unsuppressed by water quality'' (emphasis added). In the proposed rulemaking preamble, the EPA explained that the proposed requirement at 40 CFR 131.9(a)(1) requiring protection of the ''exercise of Tribal reserved rights unsuppressed by water quality'' was ''intended to result in WQS that protect reasonably anticipated future uses.'' [101] Some commenters expressed confusion regarding the meaning of unsuppressed exercise of Tribal reserved rights in the proposed regulatory text and on the distinction between that text and the preamble phrase ''protect reasonably anticipated future uses.'' In response to these commenters' concerns, the EPA added the words ''anticipated future'' to the final regulatory text, to ensure that the regulatory text clearly matches the agency's intent in adding this requirement.

Consideration of the anticipated future exercise of a Tribal reserved right is consistent with the longstanding principle that WQS establish goals for future water quality, regardless of present conditions, as discussed above. This consideration may include learning about the cultural and/or nutritional importance of the resource to the right holders, determining modern-day availability of the resource as well as alternatives to that resource, considering whether any restoration efforts that are planned or underway could impact availability of the resource, and understanding right holders' current lifestyles and practices. Determining the anticipated future exercise of a reserved right will require a case-specific evaluation to the extent supported by available data and information per 40 CFR 131.9(a). Where available data and information indicate that the existing exercise of the right is suppressed and support a quantitative determination of the anticipated future exercise of the right, the EPA expects that consideration of such data and information will lead states to revise applicable criteria, as needed, to protect the anticipated future exercise of the right. Conversely, if the state does not have sufficient available data and information to determine the anticipated future exercise of the right, after considering any information provided by right holders, it would explain that conclusion in its WQS submission, per 40 CFR 131.6(g)(1), as discussed below in section IV.E of this preamble.

One commenter requested that the EPA promulgate a minimum fish consumption rate that states must use where Tribal reserved rights to fish for subsistence apply. The EPA can provide guidance on default rates to assist states in developing criteria that take into account suppression effects but disagrees that it is appropriate to promulgate a specific rate across-the-board in this nationally applicable rule. Quantifying the anticipated future use unsuppressed by water quality is an evolving area, often requiring a complex and case-specific analysis reconciling multiple lines of evidence, in some cases including differing temporal estimates. However, the EPA agrees with commenters that the absence of data regarding an exact unsuppressed rate need not prevent a state from protecting subsistence consumption where Tribes have a right to such consumption. The EPA notes that in the absence of case-specific data and information, where a Tribal reserved right relates to subsistence fishing, the default fish consumption rate of 142 grams per day (g/day) in the EPA's 2000 methodology [102] can represent a reasonable fish consumption subsistence rate floor.

With respect to fish consumption, some commenters noted that there are other factors, beyond contamination or availability, that may affect right holders' consumption level over time, such as changes in social customs, social makeup, and dietary preferences. Additionally, some commenters noted that there are a variety of ecological and non-ecological factors other than contamination that could affect the availability of fish, including regulations that protect fish populations from overfishing. The EPA agrees that there are factors beyond contamination that could change how a reserved right is exercised, and, as explained above, the EPA intends for these other factors to be considered and discussed with right holders when determining the anticipated future exercise of the right.

Consideration of the anticipated future exercise of a Tribal reserved right unsuppressed by water quality could also include consideration of historical use of that resource. Some commenters opposing proposed 40 CFR 131.9(a)(1) conflated the proposed requirement to protect the unsuppressed use of a resource with a requirement to protect the ''heritage'' use of that resource, *i.e.,* the amount of the resource used prior to non-indigenous or modern sources of contamination and interference with natural processes. Specifically, commenters expressed concern about the use of heritage or historic rates, asserting that those are too speculative, hypothetical, and unreliable to be used in setting WQS. These commenters stated that only contemporary or current fish consumption rates should be used when establishing human health criteria, consistent with longstanding state practices. The EPA disagrees that studies of heritage rates are, as a rule, inherently speculative or unreliable such that only studies of current practices can be used in establishing WQS. Historical data are often used in

[101] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74367 (December 5, 2022).

[102] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.*

the WQS program, such as to establish reference conditions to target as a future goal in impacted waters. However, the EPA agrees that heritage data are not determinative but should be considered in the context of other available information estimating future anticipated practices and goals.

The final substantive change the EPA made between the proposed and final requirements related to suppression was to delete ''or availability of the aquatic or aquatic-dependent resource'' from the phrase ''unsuppressed by water quality or availability of the aquatic or aquatic-dependent resource.'' Some commenters addressed the inclusion of the term ''availability,'' including comments expressing concern that the proposed regulation would have required states to increase the availability of fish, and/or protect pre-contact, pristine conditions. This was not the agency's intent, and in this final rule, the EPA is removing the explicit reference to ''availability'' to avoid the implication that this rule would require states to set WQS that ignore practical realities regarding availability of resources. However, the EPA notes that consideration of ''the anticipated future exercise'' of a Tribal reserved right would include consideration of the availability of the aquatic or aquatic-dependent resource, since anticipated future exercise of the right depends in part on anticipated future availability of the resource. While this rule does not require states to increase the availability of resources, states would take into consideration under 40 CFR 131.9(a)(2) planned actions or anticipated changes that may impact resource availability and therefore the anticipated future exercise of Tribal reserved rights, such as restoration efforts that are planned or underway. This is consistent with the EPA's expectations for how states should establish other WQS.[103]

3. Criteria To Protect Tribal Reserved Rights

The final rule at 40 CFR 131.9(a)(3) establishes two new requirements related to water quality criteria. This provision requires, first, that where a state has adopted designated uses that either expressly incorporate protection of Tribal reserved rights or encompass the right, it must establish criteria to protect the right consistent with 40 CFR 131.11. In contrast to the proposal, the final requirement ties the establishment of criteria to protection of an adopted use rather than calling for establishment of criteria as a freestanding requirement. This requirement in the final rule combines parts of the requirements of proposed 40 CFR 131.9(c)(1) and proposed 40 CFR 131.9(c)(2).

As explained above in section IV.B.1 of this preamble, in this final rule the EPA has removed the proposed requirement that states must ''[d]esignate uses . . . that either expressly incorporate protection of the [T]ribal reserved rights or encompass such rights.'' Instead, the final regulatory language on designated uses in this rule specifies that states must take into consideration the use and value of their waters for protecting Tribal reserved rights in adopting or revising designated uses pursuant to 40 CFR 131.10. Accordingly, the final criteria requirement, which now appears at 40 CFR 131.9(a)(3) rather than 40 CFR 131.9(c)(2), provides that states must establish criteria to protect Tribal reserved rights ''where the State has adopted designated uses that either expressly incorporate protection of or encompass the right.'' This final criteria requirement aligns with the longstanding principle, as memorialized in 40 CFR 131.11, that states must adopt criteria that protect the designated use.

Second, the final rule clarifies that the requirements at 40 CFR 131.9(a)(3) include ''developing criteria to protect right holders using at least the same risk level (*e.g.,* cancer risk level, hazard quotient, or illness rate) as the State would otherwise use to develop criteria to protect the State's general population, paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right.'' This final provision merges the proposed requirement at 40 CFR 131.9(a)(2) that WQS must protect ''[t]he health of the right holders to at least the same risk level as provided to the general population of the State[,]'' into the provision setting forth the general requirement related to adoption of criteria discussed above. The EPA expects that this clause will apply to human health criteria, which are scientifically derived values intended to protect human health from the adverse effects of pollutants in ambient water, and will most often apply to cancer risk levels, which are a critical input in deriving protective human health criteria. The EPA's longstanding agency-wide practice has been to assume, in the absence of data to indicate otherwise, that carcinogens exhibit linear ''non-threshold'' dose-responses which means that there are no ''safe'' or no ''no-effect'' levels.[104] Therefore, the EPA recommends calculating human health criteria for carcinogens as pollutant concentrations corresponding to lifetime increases in the risk of developing cancer.

Under the EPA's 2000 Methodology, a key step in deriving human health criteria is identifying the population that the criteria should protect, sometimes referred to as the ''target'' population.[105] The 2000 Methodology explains that states could set criteria to target protection of individuals with ''average'' or ''typical'' exposure (*i.e.,* the general population), or to protect more highly exposed individuals. The 2000 Methodology goes on to recommend, with respect to carcinogens, 10^{-5} (1 in 100,000) and 10^{-6} (1 in 1 million) risk levels for the general population and further says that ''highly exposed'' subpopulations should not exceed a 10^{-4} (1 in 10,000) risk level.[106] The EPA also recommends ''that priority be given to identifying and adequately protecting the most highly exposed population.'' [107] If a state determines that a highly exposed population is not adequately protected by criteria that target protection of the general population, the EPA's 2000 Methodology recommends the adoption of more stringent criteria using alternative exposure assumptions.[108]

Prior to this rulemaking, in its 2019 decision document reversing its prior disapproval of Washington's human health criteria, the EPA took the position that it was appropriate to protect Tribal members exercising their subsistence fishing rights to a lesser degree than the state's general population. In that document, the EPA made the following assertion: ''[A] state may consider Tribes with reserved fishing rights to be highly exposed populations, rather than the target general population, in order to derive criteria, and that such consideration gives due effect to reserved fishing

[103] *See Water Quality Standards Regulatory Revisions,* 80 FR 51020, 51025 (August 21, 2015) (''When conducting a UAA and soliciting input from the public, states and authorized Tribes need to consider not only what is currently attained, but also what is attainable in the future after achievable gains in water quality are realized. EPA recommends that such a prospective analysis involve the following: Identifying the current and expected condition for a water body; evaluating the effectiveness of best management practices (BMPs) and associated water quality improvements; examining the efficacy of treatment technology from engineering studies; and using water quality models, loading calculations, and other predictive tools.'').

[104] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.*

[105] *Id.* at 2–1.

[106] *Id.* at 2–6.

[107] *Id.* at 2–2.

[108] *Id.*

rights.'' [109] As explained in the proposed rulemaking, the EPA has reconsidered this assertion and it no longer represents the agency's view.[110] For designated uses that either expressly incorporate protection of Tribal reserved rights or encompass such rights, a Tribal member utilizing such rights is more appropriately viewed as an individual with ''average'' or ''typical'' exposure because, as noted in the proposed rulemaking, Tribal members exercising reserved rights are a distinct, identifiable class of individuals holding legal rights under Federal law to resources with a defined geographic scope. In the EPA's judgment, their unique status as right holders warrants treating them as a target population for purposes of deriving human health criteria. The statements in the 2000 Methodology allowing a less stringent risk level for ''highly exposed subpopulations'' or ''subgroups''—as a subset of the general population—did not take into account the unique circumstances addressed here—*i.e.,* the unique attributes of Tribes with reserved rights as described above—in its general statements that such ''highly exposed subpopulations'' may receive less protection than chosen by states as the target population for derivation of criteria for carcinogens.

The final language in 40 CFR 131.9(a)(3) regarding risk level reflects a clarification to proposed 40 CFR 131.9(a)(2). Specifically, the EPA: (1) edited wording and sentence structure to clarify the intended meaning, (2) added examples of types of risk level inputs, and (3) explicitly stated that—when developing criteria to protect right holders—these risk level inputs are required to be paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right. These edits are intended to clarify that, where the designated use either expressly incorporates protection of Tribal reserved rights or encompasses such rights, Tribal members are the population, or one of the populations, that the designated use is designed to protect, and their health should be protected to at least the same risk level as the state would have provided to the general, non-right holder population if there were no applicable Tribal reserved rights in that location. These changes are explained further below in the context of responses to comments received on this point.

A few commenters expressed concerns that, under the proposed rulemaking, states would be required to revise all of their applicable criteria including criteria for the protection of aquatic life and aquatic-dependent wildlife. That was neither the EPA's intent with the proposal, nor is it the anticipated effect of the final rule. The agency anticipates that the new requirements in 40 CFR 131.9(a) will not generally necessitate more stringent criteria to protect aquatic life, wildlife, or primary contact recreation than already required by 40 CFR 131.11.

This final rule builds on requirements in the existing Federal WQS regulation at 40 CFR part 131 regarding adoption of designated uses and criteria. In accordance with the interim goal specified by CWA section 101(a)(2) of ''water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water,'' the existing Federal WQS regulation requires that state WQS provide for protection and propagation of fish, shellfish and wildlife, and recreation in and on the water, wherever attainable.[111] With respect to aquatic life and wildlife criteria, the EPA anticipates that for many aquatic and aquatic-dependent resources to which Tribes have reserved rights, the level of protection for the species resulting from application of the EPA's existing Federal WQS regulation, without specific consideration of reserved rights, is already consistent with protection of those resources. For example, where a Tribe has the right to fish for subsistence, the existing WQS regulation already requires the state to protect fish and other aquatic species with aquatic life criteria.[112] Protection of human health from fish consumption is discussed separately below.

For Tribal ceremonial practices involving activities where the principal risk is from immersion in and potential ingestion of water, the EPA anticipates that pollutant exposure would be indistinguishable from exposure through primary contact recreation (*e.g.,* swimming), and state criteria to protect primary contact recreation would therefore be protective of such Tribal practices.

Conversely, water quality criteria to protect human health for fish/shellfish and water consumption uses that were written with a state's general population in mind may not protect Tribal consumers of those resources who have higher consumption rates and therefore are exposed to greater risk. In states where right holders assert reserved fishing rights and the states' human health criteria are currently based on protection of the states' general population, the requirement the EPA is finalizing at 40 CFR 131.9(a)(3) may result in more stringent criteria than had been explicitly required by the existing Federal WQS regulation, to ensure that the right holders are protected by criteria developed using at least the same risk level (*e.g.,* cancer risk level, hazard quotient, or illness rate) as the state would otherwise use to develop criteria to protect the state's general population, paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right. For example, a state with a fishing designated use may have established its human health criteria for carcinogens using a 1 in 1 million (10^{-6}) cancer risk level and exposure inputs (including a fish consumption rate) representative of its general population, which consumes one fish meal per week. In that scenario, a member of a Tribe in that state exercising the Tribe's reserved right to fish for subsistence who consumes ten fish meals per week would be protected at a 1 in 100,000 (10^{-5}) cancer risk level, an order of magnitude less than the cancer risk level the state had determined was appropriate for its general population. In revising those criteria upon an assertion of that right by the right holders and supported by available data and information, the state

[109] U.S. EPA, Letter and enclosed Technical Support Document from Chris Hladick, Regional Administrator, EPA Region 10, to Maia Bellon, Director, Department of Ecology, Re: EPA's Reversal of the November 15, 2016 Clean Water Act Section 303(c) Partial Disapproval of Washington's Human Health Water Quality Criteria and Decision to Approve Washington's Criteria (May 10, 2019), p. 23.

[110] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74370 (December 5, 2022).

[111] 40 CFR 131.10 requires that, where waters are designated for less than the full CWA section 101(a)(2) use, that designation be supported by a use attainability analysis (UAA) demonstrating that attaining the use is not feasible. These waters must be designated for the highest attainable use. 40 CFR 131.20 requires these use designations to be reviewed at every triennial review and revised when new information indicates that the uses specified in section 101(a)(2) of the CWA are attainable.

[112] In some cases, 40 CFR 131.9(a)(3) may prompt a state to consider adjusting aquatic life criteria in a certain area to protect a culturally important species, consistent with the EPA's recommended definition of ''protection of aquatic organisms and their uses'' as, in part, prevention of unacceptable effects on ''commercially, recreationally, and other important species.'' (USEPA. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. U.S. Environmental Protection Agency, Office of Water, Washington, DC PB85–227049). Additionally, it may encourage efforts to advance the scientific understanding of pollutant impacts to wildlife and plants that have not been the historic focus of criteria development.

would revise its criteria to afford the right holders a 1 in 1,000,000 (10^{-6}) cancer risk level, which is the level of protection the state had determined was appropriate for its general population. This revision would have the effect of protecting the state's general population at a 1 in 10,000,000 (10^{-7}) cancer risk level given their lower fish consumption level.

Some commenters opposed the proposed requirement to protect right holders to at least the same risk level as used to calculate criteria to protect the state's general population, asserting that the CWA does not prescribe precisely how a state must establish its WQS so long as WQS are protective. The EPA does not intend for this rule to dictate specific outcomes to states. Under this rule, states maintain their statutory role set forth in CWA section 303(c) in establishing WQS. The EPA maintains its CWA section 303(c) statutory oversight role in ensuring that WQS are meeting the requirements of the Act, including that WQS are such as to protect public health and enhance the quality of water. In exercising its oversight function, the EPA also brings substantial technical expertise to the topic of criteria development. In section 304(a) of the CWA, Congress explicitly charged the EPA with developing recommended water quality criteria based on the latest scientific knowledge related to health and welfare.[113] As the EPA explained in its 2015 update to its recommended ambient water quality criteria for the protection of human health, ''[w]ater quality criteria developed under Section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects.'' [114] These recommended criteria are not legally binding, and states have discretion to modify the criteria, where appropriate, to reflect site-specific conditions or criteria based on other scientifically defensible methods.

Contrary to the characterization of the proposed requirements in some of the comments, the EPA did not intend to suggest that the requirement to develop criteria to protect right holders using at least the same risk level as the state would otherwise use to develop criteria to protect the state's general population would result in criteria that protect right holders and the general population equally. The EPA recognizes that risk increases with exposure and based on susceptibility factors such as age or lifestage, pre-existing disease, genetic variation, or co-exposures. As the EPA explained in its 2000 Methodology,[115] ''. . . the incremental cancer risk levels are *relative,* meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (*e.g.,* intake rates, body weights). When these exposure parameter values change, so does the relative risk.'' (Emphasis in original). This concept is illustrated in the example above. The EPA added clarifying text to 40 CFR 131.9(a)(3) providing examples of types of risk level inputs (''*e.g.,* cancer risk level, hazard quotient, or illness rate'') to highlight that it is the risk level input *itself* that must be equal in the criteria calculations, not that the state is required to establish criteria that protect right holders and the general population equally (*i.e.,* if the state uses a 10^{-6} cancer risk level to calculate criteria to protect the general population, the state must also use a 10^{-6} cancer risk level to establish water quality criteria to protect the Tribal reserved right, where the state has adopted designated uses that either expressly incorporate protection of or encompass the right). To further address the confusion expressed by some commenters, the EPA also added clarifying text to 40 CFR 131.9(a)(3) noting that appropriate exposure inputs must be used in each of these calculations: when calculating criteria to protect the general population, the state's chosen risk level (*e.g.,* 10^{-6} cancer risk level) would be paired with exposure inputs (*e.g.,* fish consumption rate) representative of the general population, whereas when establishing water quality criteria to protect a Tribal reserved right, that same chosen risk level must be ''paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right.'' In other words, the EPA is simply requiring that right holders, in areas where they have reserved rights, be protected using the same (or a more stringent) risk level input (*e.g.* cancer risk level) to calculate criteria as is used to calculate criteria to protect the general population in areas where there are no Tribal reserved rights reserved to Tribes by treaty, Federal statute, or Executive order. As explained above, the practical effect is that in some situations in a waterbody with Tribal reserved rights, the general population will be even more protected (that is, receive protection to a more stringent risk level) than if there were no Tribal reserved rights in that waterbody. This approach does not prescribe the state's overall approach to risk management policy, but rather ensures that right holders receive the level of protection (that is, they are exposed to the same risk level) consistent with the state's risk management decision for the general population in the absence of reserved rights.

In the proposed rulemaking, the EPA explained that it anticipated the primary application of the requirement to protect the health of the right holders with criteria developed using at least the same risk level as the state would otherwise use to develop criteria to protect its general population would be in establishing human health criteria for toxic pollutants to protect Tribal reserved rights to fish for subsistence. The EPA requested comment on whether there may be other situations where this provision could apply. While the EPA received general support for this requirement, commenters did not raise, and the EPA is not currently aware of, situations other than human health criteria for toxic pollutants where the level of risk may be different for right holders versus the general population.

The EPA is not mandating any specific risk level in this rule. As explained in the EPA's 2000 Methodology,[116] with respect to carcinogens, 10^{-5} (1 in 100,000) and 10^{-6} (1 in 1 million) risk levels may be reasonable for the general population.[117] Some commenters stated that the final rule should require Tribal fishing right holders to be protected to a 10^{-6} cancer risk level to provide a baseline level of protection for subsistence fishing rights, consistent with the EPA's recommendation for the general population and with environmental justice principles. The EPA disagrees that an across-the-board requirement of 10^{-6} is appropriate. In this final rule, states maintain the discretion to utilize a cancer risk level that is within a reasonable risk management range. Per the 2000 Methodology, the EPA recommends protecting the general population using a cancer risk level of

[113] *See* CWA section 304(a).

[114] USEPA, Notice of Availability: Final Updated Ambient Water Quality Criteria for the Protection of Human Health, 80 FR 36986 (June 29, 2015).

[115] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.* p. 2–7.

[116] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.*

[117] *Id.* at 2–6.

10^{-5} or 10^{-6} to derive criteria, recognizing the need to protect highly exposed or sensitive populations, as appropriate. Therefore, consistent with the EPA's longstanding recommendation for states' general populations in the 2000 Methodology, the EPA also considers 10^{-5} acceptable to protect right holders in areas where they are exercising reserved rights relevant to the activities that human health criteria for toxic pollutants are designed to protect. This approach does not prescribe a risk management decision to the state but rather ensures that right holders benefit from the same level of protection that the state has chosen to protect the general population for a given designated use.

One commenter requested that the EPA establish a minimum fish consumption rate for protecting rights to subsistence fishing. While the EPA is declining to establish a required minimum level of protection, as noted in section IV.B.2 of this preamble, the EPA's national recommended default fish consumption rate of 142 g/day for subsistence fishers can represent a reasonable fish consumption subsistence rate floor.[118]

[118] The EPA evaluated whether 142 g/day is still representative of current consumption rates for highly exposed groups, as noted in the 2000 Methodology. Post-2000 consumption surveys of high fish consuming populations (*e.g.,* Tribes and Asian Pacific Islanders) resulted in mean fish consumption rates ranging from 18.6 g/day to 233 g/day and 90th percentile fish consumption rates ranging from 48.9 g/day to 528 g/day. 142 g/day falls within these ranges and therefore, 142 g/day appears to still be representative of current consumption rates for certain highly exposed groups, albeit possibly on the low end. *See:* Polissar, N.L., Salisbury, A., Ridolfi, C., Callahan, K., Neradilek, M., Hippe, D.S., and Beckley, W.H. (2016). *A Fish Consumption Survey of the Nez Perce Tribe.* The Mountain-Whisper-Light Statistics, Pacific Market Research, Ridolfi, Inc. *https://www.epa.gov/sites/production/files/2017-01/documents/fish-consumption-survey-nez-perce-dec2016.pdf;* Polissar, N.L., Salisbury, A., Ridolfi, C., Callahan, K., Neradilek, M., Hippe, D.S., and W.H. Beckley. (2016). *A Fish Consumption Survey of the Shoshone-Bannock Tribes.* The Mountain-Whisper-Light Statistics, Pacific Market Research, Ridolfi, Inc. *https://www.epa.gov/sites/production/files/2017-01/documents/fish-consumption-survey-shoshone-bannock-dec2016.pdf;* Seldovia Village Tribe. (2013). *Assessment of Cook Inlet Tribes Subsistence Consumption.* Seldovia Village Tribe Environmental Department; Suquamish Tribe. (2000). *Fish Consumption Survey of The Suquamish Indian Tribe of The Port Madison Indian Reservation, Puget Sound Region.* Suquamish, W.A.; Sechena, R., Liao, S., Lorenzana, R., Nakano, C., Polissar, N., Fenske., R. (2003). *Asian American and Pacific Islander seafood consumption—a community-based study in King County, Washington.* J of Exposure Analysis and Environ Epidemiology. (13): 256–266; Lance, T.A., Brown, K., Drabek, K., Krueger, K., and S. Hales. (2019). *Kodiak Tribes Seafood Consumption Assessment: Draft Final Report,* Sun'aq Tribe of Kodiak, Kodiak, AK. *http://sunaq.org/wp-content/uploads/2016/09/Kodiak-Tribes-Seafood-Consumption-Assessment-DRAFT-Final-Report-26Feb19-FINAL.pdf.*

C. Designated Use Revisions, WQS Variances, and Existing Uses

As discussed above in section IV.B.1 of this preamble, in this final rule at 40 CFR 131.9(a)(1), the EPA is requiring that states consider the use and value of their waters for protecting Tribal reserved rights in adopting or *revising* designated uses, including use revisions that are required to be supported by a use attainability analysis, per 40 CFR 131.10(g) and (j). The EPA is not adding language in this final rule addressing WQS variances or existing uses and is not making changes to those sections of the existing 40 CFR part 131 regulation (*i.e.,* §§ 131.14 and 131.10, respectively).

The proposed rulemaking did not include any provisions related specifically to designated use revisions (such as provisions related to use attainability analyses), WQS variances, or existing uses. Instead, the EPA requested comment on whether and how states can revise designated uses in accordance with 40 CFR 131.10, while also ensuring the protection of Tribal reserved rights. Additionally, the EPA requested comment on whether it should specify in 40 CFR 131.9 how other WQS provisions, such as WQS variances under 40 CFR 131.14, should be used to ensure protection of Tribal reserved rights. The EPA noted that it was ''not proposing to modify the existing language in [the existing 40 CFR part 131] sections'' and was ''not reopening them for comment.'' [119] Rather, the agency was considering whether ''potential discrete additions'' to the proposed regulatory framework may be necessary.

Some commenters recommended that the final rule prohibit states from revising designated uses or adopting WQS variances in waters where Tribes hold reserved rights, especially based on factors related to economic feasibility. Some commenters recommended that a WQS variance or designated use removal should only be allowed in extremely limited circumstances, with express written consent of right holders, and/or that right holders should be able to impose conditions on designated use revisions. Conversely, some commenters stated that designated use revisions and WQS variances must be allowed in waters with applicable Tribal reserved rights, consistent with the framework in the EPA's existing WQS regulation, and that any restriction of these approaches would be inconsistent with the CWA.

[119] *See Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights Proposed Rule,* 87 FR 74361, 74373 (December 5, 2022).

Nothing in this final rule alters the existing regulatory requirements at 40 CFR 131.10 related to use attainability analyses. With respect to designated use revisions and use attainability analyses, CWA section 101(a)(2) contains the phrase ''wherever attainable,'' which the EPA has implemented in 40 CFR 131.10(g) and (j) as allowing a state to designate uses that do not include the uses specified in section 101(a)(2) of the Act, to remove a 101(a)(2) use that is not an existing use, or to designate a subcategory of such a use if the state conducts a use attainability analysis demonstrating that attaining the use is not feasible because of one or more factors at 40 CFR 131.10(g). After a state demonstrates that a use is not attainable for a certain water, 40 CFR 131.10(g) also requires the state to adopt ''the highest attainable use'' of that water, which is the aquatic life, wildlife, or recreation use that is both closest to the CWA 101(a)(2) use and attainable, as defined at 40 CFR 131.3(m). The final rule at 40 CFR 131.9(a)(1) requires states to consider the use and value of their waters for protecting Tribal reserved rights in revising designated uses, including use revisions that are required to be supported by a use attainability analysis, per 40 CFR 131.10(g) and (j). The EPA recognizes that some of the factors at 40 CFR 131.10(g) may be amenable to greater consideration than others. The EPA is available to help work with any states that are contemplating revising designated uses that expressly incorporate protection of Tribal reserved rights or encompass such rights.

Regarding WQS variances, the EPA has concluded there is no compelling reason to make additions to the Federal regulation related to WQS variances to address Tribal reserved rights, at this time. Therefore, this final rule does not explicitly address WQS variances, nor does it add to the existing WQS regulation at 40 CFR 131.14 governing WQS variances. While the EPA acknowledges the concerns raised by commenters regarding the potential impacts of WQS variances on reserved rights, it disagrees with comments asserting that the current regulatory provisions at 40 CFR 131.14 are insufficient to protect water quality necessary to support reserved rights. The existing WQS regulation at 40 CFR 131.14(b)(1)(ii) requires that WQS variances ''shall not result in any lowering of the currently attained ambient water quality, unless a WQS variance is necessary for restoration activities.'' Therefore, allowing WQS variances in waters where Tribal

reserved rights apply does not result in degraded water quality; rather, WQS variances are a time-limited tool that states may use to improve water quality over time. WQS variances provide states with time and flexibility to make incremental water quality improvements where the water body is not currently attaining WQS, with accountability measures to ensure that such improvements will occur. At the end of the specified variance term, the underlying designated use and criterion apply and, thus, WQS variances do not permanently revise the protections for a water body. Nothing in this final rule alters the existing regulatory requirements related to WQS variances.

Finally, some commenters requested clarification about how this rule relates to the existing WQS regulation governing protection of existing uses. The existing WQS regulation defines existing uses at 40 CFR 131.3(e) as ''those uses actually attained in the water body on or after November 28, 1975, whether or not they are included in the water quality standards.'' The EPA did not propose to modify the definition of existing uses in the proposed rulemaking and is not altering that definition in this final rule. If use of an aquatic or aquatic-dependent resource pursuant to a Tribal reserved right is presently being attained, the EPA's existing regulation at 40 CFR 131.10(i) requires states to revise their WQS to reflect the presently attained use. For example, if a Tribe has a right to gather an aquatic plant in a state waterbody and that use is presently attained, state WQS must reflect that as a designated use, per 40 CFR 131.10(i), and thus this resource should be protected in accordance with 40 CFR 131.9(a).

D. General WQS Policies

This final rule does not change the existing WQS regulation at 40 CFR 131.13 and 131.15 governing establishment of general WQS policies and permit compliance schedule authorizing provisions. The proposed rulemaking requested comment on whether the EPA should specify how general WQS policies, such as mixing zone policies, or permit compliance schedule authorizing provisions, should be used to ensure protection of Tribal reserved rights. The agency decided in this final rule not to revise the existing Federal regulation or add new regulatory requirements for general WQS policies adopted by states, such as mixing zone policies, or for permit compliance schedule authorizing provisions. Decisions about specific mixing zones or the use of compliance schedules in areas where Tribal reserved rights apply would be made case-by-case by the applicable NPDES permitting authority.

Some commenters recommended that the final rule require a state proposing to include a schedule of compliance in an NPDES permit discharging to a water with Tribal reserved rights demonstrate that it has conducted timely outreach to Tribe(s) whose rights are impacted, obtained written consent from the Tribe(s), and implemented reasonable conditions as requested by the Tribe(s). Compliance schedules in NPDES permits serve as a tool for dischargers to obtain additional time to implement actions that will lead to compliance with water quality-based effluent limits based on the applicable WQS. While the EPA's existing regulation at 40 CFR 131.15 requires states to include provisions in their WQS that authorize the use of compliance schedules if they intend to include compliance schedules in NPDES permits, the eventual compliance schedules that may be issued in specific NPDES permits discharging in areas where Tribal reserved rights apply are governed by the NPDES regulation at 40 CFR 122.47. The NPDES regulation, which is not affected by this final rule, requires compliance with water quality-based effluent limits ''as soon as possible'' and if an individual compliance schedule exceeds one year, the permitting authority must include interim requirements and the dates for their achievement. Additionally, interested persons such as right holders would have an opportunity to comment on any draft NPDES permits that are discharging in areas where Tribal reserved rights apply, subject to the NPDES regulation public participation requirements.[120]

E. Roles, Responsibilities, and WQS Submission Requirements

An important objective of the changes set forth in this final rule is to ensure that, in implementing CWA section 303(c), the states' and EPA's roles with respect to Tribal reserved rights in the WQS context are clearly delineated and explained. This section clarifies respective roles and responsibilities and describes the relevant regulatory language at 40 CFR 131.6(g), 131.9(b) and (c) of the final rule.

The EPA received many comments related to the roles of the EPA and/or other parts of the Federal Government, states, and right holders in implementing this rule, particularly with respect to identifying and interpreting Tribal reserved rights. Some commenters asserted that the rule should provide a clear and specific role for right holders in identifying and interpreting their rights. Many commenters expressed concerns regarding states' ability, both as a legal and practical matter, to identify and interpret rights, and many commenters stated that the Federal Government, and not States, should be interpreting and applying relevant treaties and other legal instruments reserving Tribal rights. The EPA disagrees it is the Federal Government's sole responsibility to interpret relevant treaties, statutes, and Executive orders, and provide those interpretations to states. While the EPA intends to work closely with states and right holders, where requested, in identifying and interpreting relevant rights, states are already bound to comply with Tribal reserved rights codified in Federal law even absent a Federal position on such rights.

As explained above in section III of this preamble, this final rule is premised on right holders asserting rights that they have identified as relevant in the WQS context, thus providing a specific role for right holders in identifying and interpreting their rights in the first instance. Accordingly, the EPA disagrees that this rule would place a burden on states to interpret and analyze all potentially relevant treaties, statutes, or Executive orders that reserve rights within their respective state. The operative inquiry for this rule is whether a treaty, statute, or Executive order reserves a right to a CWA-protected aquatic or aquatic-dependent resource, and as such, a full analysis of every legal instrument would not be necessary. As a practical matter, where a state chooses to undertake an analysis of asserted rights, there are interpretive resources available. Many Tribal reserved rights reflected in treaties, statutes, or Executive orders have been interpreted by courts and/or applied by the Federal Government, States, and Tribes for many years. This information regarding interpretation and application of the rights is available to right holders for purposes of asserting relevant rights in the WQS context and to the EPA and states when engaging with right holders. Additionally, the U.S. Department of Agriculture and the U.S. Department of Interior, working with Oklahoma State University, have developed a publicly available, searchable database of Tribal treaties that can provide a starting point

[120] *See, e.g.,* 40 CFR 124.10.

for research on potentially applicable Tribal reserved rights.[121]

In relation to identifying or interpreting Tribal reserved rights, final 40 CFR 131.9(b) provides that at any time in the WQS development process, a state or right holder may request EPA assistance with evaluating Tribal reserved rights. The EPA added this provision to the final rule in response to comments and in anticipation that, even with the clarifications provided in this final rule with respect to roles and expectations, states and right holders may still have questions regarding the applicability and implementation of the rule's requirements in light of particular asserted rights. The EPA will work collaboratively with states and right holders, engaging other Federal agencies as appropriate, to evaluate the available information and help states to develop WQS to protect applicable rights. In addition, the EPA periodically offers opportunities for Tribes to learn more about the WQS process and regulations, should they not yet have experience in this field.

Some commenters requested clarification about how disputes or disagreements between states and Tribes, or different Tribes holding the same rights, would be resolved. For example, some commenters noted that there may be instances when a right holder does not agree with the EPA or a state's conclusions about protecting their rights, and requested clarity on how the EPA will evaluate the right holder's position if it asserts during consultation that state WQS do not consider or protect applicable Tribal reserved rights. In some cases, the nature and precise location of some rights might not be certain, or new information may come to light that challenges prior assumptions. Much of the existing WQS development process depends on navigating situations in which consensus or clarity is lacking or where new information emerges, such as the appropriate use of a waterbody or what constitutes sound science. Where there is a lack of clarity or disagreement regarding relevant reserved rights, the EPA can work with states, right holders, and Federal partners to interpret the right, as appropriate. The CWA requirement to review WQS every three years also provides an opportunity to revisit WQS issues characterized by limited data or disputes.

The EPA did not propose a formal dispute resolution process for addressing and resolving such disputes and is not including one in this final rule.[122] In considering these comments, the EPA concluded that a formal dispute resolution mechanism would not be an efficient or practically implementable means to handle such disagreements. Rather, the agency is adding additional regulatory language at 40 CFR 131.9(b) to clarify its commitment to engaging early and partnering with states and right holders in implementing the rule's requirements. The agency intends to engage early in states' WQS processes where Tribes assert potential reserved rights to prevent or resolve disputes to the extent practicable.

The EPA recognizes that there may be situations where disputes about the relevance of the rights and/or WQS needed to protect the rights may prove intractable, and in some cases states may need to move forward with the development of their WQS in the absence of consensus. In such cases, where the state submits new or revised WQS to the EPA, the state should explain in its submission why it believes it lacks ''available data and information'' to resolve the dispute and the EPA will review all of the available information submitted pursuant to 40 CFR 131.6(g) and decide whether to approve or disapprove the submission in the same way the EPA currently makes decisions when there are disagreements between different parties on WQS protections.

Where a right holder has asserted a relevant right and 40 CFR 131.9 applies, 40 CFR 131.6(g) addresses states' obligations to provide information regarding that right and how the state considered it in establishing new or revised WQS. In the proposed rulemaking at 40 CFR 131.6(g), the EPA proposed requiring states to submit, where applicable, ''[i]nformation about the scope, nature, and current and past use of the [T]ribal reserved rights, as informed by the right holders[.]'' Many commenters disagreed with the wording of proposed 40 CFR 131.6(g), asserting that the phrase ''as informed by the right holders'' was ambiguous and that it was not clear whether or how this required states to solicit input from right holders, or what it required states to do with that input. Commenters also expressed questions and concerns with the EPA's expectations from states as far as gathering and submitting information about reserved rights, echoing the comments described above raising the appropriate role for both states and right holders in that process.

In response to these comments, the EPA revised the wording of 40 CFR 131.6(g) in the final rule to require that, where 40 CFR 131.9 applies, *i.e.,* where Tribal reserved rights apply and right holders have asserted their rights for consideration in establishment of WQS, the supporting information that the state must provide to the EPA includes ''[a]ny information provided by right holders about *relevant* Tribal reserved rights and documentation of how that information was considered,'' (emphasis added) along with data and methods used to develop the WQS. As explained in section IV.G. of this preamble below, for example, Tribal reserved rights related to human health, such as fish consumption, would be relevant to WQS related to protection of human health; rights related to human health would not be relevant to WQS targeted at protection of aquatic life or industrial uses.

To further ensure that right holders can meaningfully engage in states' WQS processes and in response to comments on this point, the EPA added the requirement for states to include in their CWA section 303(c) submission to the EPA documentation of how the information provided by right holders was considered in establishment of WQS. The EPA recommends that such documentation include how any information provided by right holders was integrated into the state's WQS; any substantive suggestions the right holders made that the state did not adopt; and the state's justification for not adopting those suggestions. The EPA also acknowledges that states can only provide information to fulfill 40 CFR 131.6(g)(1) that they have received. The

[121] Oklahoma State University Libraries. 2003. Tribal Treaties Database (public beta). *https://treaties.okstate.edu/.*

[122] Several commenters cited the existing WQS dispute resolution provision at 40 CFR 131.7. *See* 40 CFR 131.7(a) (''Where disputes between States and Indian Tribes arise as a result of differing water quality standards on common bodies of water, the EPA Regional Administrator . . . will be responsible for acting in accordance with the provisions of this section.''). One commenter pointed to that provision as a potential model for addressing disputes between states and Tribes, or Tribes and Tribes, regarding reserved rights; one commenter pointed to that provision, which was added pursuant to CWA section 518(e), as evidence that where Congress intended for the EPA to be the arbiter of disputes between states and Tribes, it said so explicitly; and one commenter questioned whether that provision would apply here. The EPA notes that 40 CFR 131.7 was added pursuant to direction from Congress set forth in CWA section 518(e), and the agency is not purporting to rely on that regulation in implementing this rule. 40 CFR 131.7 is narrowly focused on disputes between states and Tribes authorized to administer a WQS program arising as a result of differing, existing WQS on common bodies of water. Accordingly, this dispute resolution mechanism would not apply here, where disputes between a state and Tribe(s) would relate to the state's WQS, as opposed to differing state and Tribal WQS. As explained above, the EPA is not codifying a new dispute resolution provision addressing disputes relating to Tribal reserved rights. Rather, the EPA is expressing its commitment to engage on a more informal basis to prevent or resolve disputes where needed.

EPA recommends that where right holders did not respond or declined to engage, the state's record should document the opportunities afforded to right holders to engage in the WQS process and should memorialize where Tribal engagement efforts did not identify any Tribal assertions of relevant rights.

F. The EPA's Tribal Engagement and Consultation

This final rule at 40 CFR 131.9(c) requires the EPA to initiate the Tribal consultation process with right holders that have asserted their rights for consideration in establishment of WQS, as discussed in section IV.B. of this preamble above. That is, the relevant EPA regional office will notify the right holders of the opportunity for government-to-government consultation when taking actions under this rule. Government-to-government consultation between the EPA and right holders will aid the EPA in evaluating whether WQS submissions protect applicable Tribal reserved rights. The EPA updated the wording of the proposed consultation provision (previously at proposed 40 CFR 131.9(b)) for consistency with the changes to 40 CFR 131.9(a) and moved this provision to 40 CFR 131.9(c) in the final rule given the other changes that the EPA made to 40 CFR 131.9 from the proposed rulemaking. This final provision largely tracks proposed 40 CFR 131.9(b), with three clarifying edits.

First, the final rule clarifies that the EPA ''will initiate the Tribal consultation process.'' In the proposed rulemaking, the EPA proposed to ''initiate [T]ribal consultation'' with right holders when the EPA is reviewing a relevant WQS submission. This edit is being made to clarify that the EPA will notify right holders that have asserted their rights that they have the opportunity to consult with the EPA on the EPA action to approve or disapprove submitted WQS. It will then be the right holder's decision whether or not to proceed with Tribal consultation. If a right holder does not respond affirmatively to a Tribal consultation notification from the EPA, consultation would not advance beyond this notification step.[123]

The second clarifying edit the EPA made to 40 CFR 131.9(c) was to specify that the EPA will initiate the Tribal consultation process with right holders ''that have asserted their rights,'' to conform with the changes the EPA made to 40 CFR 131.9(a). In addition to initiating the Tribal consultation process with right holders that have asserted their rights for consideration in establishment of WQS per final 40 CFR 131.9(c), the EPA intends to initiate the Tribal consultation process with all federally recognized Tribes potentially affected by an EPA action per the EPA's consultation policy,[124] including any potentially affected right holders that have not asserted those rights for consideration in establishment of WQS.

Finally, 40 CFR 131.9(c) also notes that the EPA will initiate the Tribal consultation process in determining whether state WQS ''are consistent with'' final 40 CFR 131.9(a), as opposed to ''protect applicable Tribal reserved rights in accordance with'' proposed 40 CFR 131.9(a). The EPA made this change to streamline 40 CFR 131.9 and keep the operative requirements in the same regulatory section.

Some commenters stated that to ensure consultation is meaningful and the state has adequate time to fully consider critical information provided by right holders, the EPA should consult with Tribes earlier in the WQS development process. The EPA added 40 CFR 131.9(b) in response to these comments to clarify that the EPA is available to assist both states and right holders in evaluating Tribal reserved rights at any time, upon request, and will engage potential right holders whenever it provides assistance to the state with evaluating Tribal reserved rights. It is the EPA's policy to consult on a government-to-government basis with federally recognized Tribal governments when EPA actions or decisions may affect Tribal interests.[125]

Some commenters expressed the view that to ensure the EPA's consultation is meaningful, the final rule should specify consultation procedures, specify minimum thresholds of engagement, or specifically invite right holders to contribute to or collaborate on WQS to protect their rights. In light of different Tribes' varying preferences for consultation procedures, the EPA was not able to identify any universally applicable procedures or thresholds of engagement that would be appropriate to include in regulatory text. The EPA intends to implement consultation consistent with its existing consultation policies and procedures.

Some commenters stated that states or other stakeholders should be engaged in the EPA's consultation with right holders. Consultation with federally recognized Tribes, consistent with the EPA's consultation policy,[126] is government-to-government consultation between the Tribe and the EPA. It would therefore not be appropriate to add other parties to those consultations. However, in the WQS context, the EPA generally recommends close coordination between the state, the EPA, and right holders to maximize transparency, collaboration, and mutual understanding between all parties.

Finally, some commenters requested that the EPA provide a mechanism to maintain confidentiality of information Tribes provide during consultation upon request. As explained in section IV.B of this preamble, the EPA is subject to the FOIA, and accordingly, FOIA disclosure requirements would apply to information provided to the EPA by Tribes.

G. The EPA's Oversight Authority of New and Revised State WQS

40 CFR 131.5(a) sets forth the requirements that the EPA looks for in reviewing and approving or disapproving state WQS. The final rule amends the list of requirements at 40 CFR 131.5(a) to include, ''[w]here applicable, whether State adopted [WQS] are consistent with § 131.9.''

In the proposed rulemaking, the EPA proposed adding 40 CFR 131.5(a)(9), which provided that, as part of its review, the EPA would determine ''[w]hether any State adopted water quality standards protect [T]ribal reserved rights, where applicable, consistent with § 131.9.'' The EPA received several comments on the language of 40 CFR 131.5(a)(9), including comments requesting clarification on how the EPA would apply that provision. In the final rule, the EPA made two sets of changes to proposed 40 CFR 131.5(a)(9) to add greater clarity and for consistency with revisions made to 40 CFR 131.9.

First, the EPA revised the clause ''protect [T]ribal reserved rights . . . consistent with § 131.9,'' to instead provide in final 40 CFR 131.5(a)(9) that the EPA will determine whether WQS ''are consistent with § 131.9.'' Because 40 CFR 131.9 lays out the operative requirements for states to apply where Tribal reserved rights have been asserted and are applicable to the establishment of WQS, the clause ''protect [T]ribal reserved rights'' was

[123] Where a right holder does not respond or declines Tribal consultation, the EPA will proceed with reviewing a state WQS submittal in accordance with 40 CFR 131.5, including ''[w]here applicable, whether State adopted water quality standards are consistent with § 131.9,'' consistent with final § 131.5(b)(9).

[124] USEPA 2023. EPA Policy on Consultation with Indian Tribes. *https://www.epa.gov/sites/default/files/2013-08/documents/cons-and-coord-with-indian-tribes-policy.pdf.*

[125] *Id.*

[126] *Id.*

unnecessary and the EPA is removing it for clarity and simplicity.

Second, the EPA made two changes to clarify when the agency would evaluate compliance with 40 CFR 131.5(a)(9). The proposed rulemaking provided that the EPA would evaluate whether ''any'' state-adopted WQS protected reserved rights, ''where applicable,'' consistent with 40 CFR 131.9. The EPA deleted ''any'' and moved ''where applicable'' to the beginning of the clause. The EPA made these changes to clarify that WQS must only be consistent with 40 CFR 131.9 where those WQS are applicable to the exercise of the Tribal reserved right in question. If a state has a designated use that encompasses a Tribal reserved right, then the criteria applicable to that use must protect that right. For example, a Tribal reserved right to gather aquatic resources may be encompassed by a state's broadly defined aquatic life use. If so, then the aquatic life criteria must protect those aquatic resources and/or right holders that are consuming those resources, as appropriate. This revision is intended to address concerns that the provision as proposed could be read to require consideration and protection of Tribal reserved rights in every WQS revision in the future. The EPA does not intend for this rule to blur the lines between the different WQS that states establish to protect different uses of their waters. For example, this rule would not require WQS intended to protect human health uses such as fish consumption to also protect aquatic life uses such as survival, growth, and reproduction of fish or shellfish.

H. Triennial Reviews

This final rule modifies the existing regulation governing state review and revision of WQS at 40 CFR 131.20(a) to require that the triennial review process include an evaluation of whether there is any new information that needs to be considered about Tribal reserved rights applicable to waters subject to the state's WQS and whether WQS need to be revised to be consistent with 40 CFR 131.9.

In the proposed rulemaking, the EPA proposed modifying 40 CFR 131.20(a) to require that state triennial reviews include ''evaluating whether there are [T]ribal reserved rights applicable to State waters and whether water quality standards need to be revised to protect those rights pursuant to § 131.9.'' Some commenters indicated that it is overly burdensome to require states to re-evaluate Tribal reserved rights at every triennial review. In response to these comments, the EPA added the clause ''new information available . . . that needs to be considered'' to clarify that states are not expected to independently evaluate whether there are applicable Tribal reserved rights to consider at every triennial review. Rather, in conjunction with the revisions to 40 CFR 131.9(a), states are expected to evaluate whether a right has been newly asserted since the state's last triennial review or there is new information relevant to the protection of a previously asserted Tribal reserved right.

This regular review of WQS and evaluation of new information to determine whether WQS need to be modified is consistent with the triennial review requirement in CWA section 303(c)(1). In order for these new requirements and the existing requirements at 40 CFR 131.20(a) to be meaningful, states must conduct regular triennial reviews and must provide opportunities for interested and affected parties to bring forward new information for the state's consideration. The CWA makes clear that each state's fulfillment of their triennial review responsibilities is an integral part of the WQS paradigm.[127] The EPA strongly urges states to fulfill their triennial review requirements.

Many commenters stated that it should be the Federal Government's rather than states' responsibility to periodically re-evaluate Tribal reserved rights, and that the EPA should inform states of any new information relevant for WQS. As discussed above, final §§ 131.20(a) and 131.9, are intended to clarify the expectation that at each triennial review states consider and evaluate new assertions of Tribal reserved rights and any new data and information relevant to protection of asserted rights. If the EPA becomes aware of any new information relevant to the protection of applicable Tribal reserved rights, it will endeavor to inform states of that information as expeditiously as possible.

One commenter asserted that proposed 40 CFR 131.20(a) was redundant with their state's existing process for engaging Tribes. Some commenters recommended that the EPA specify a process to ensure that states work directly with right holders early in the triennial review process, separate from and well before engagement with the general public. As explained in section IV.E of this preamble, the EPA revised 40 CFR 131.6(g) in the final rule to require that, where 40 CFR 131.9 applies, state WQS submissions to the EPA include information provided by right holders. The EPA recommends that states provide opportunities for known and potential right holders to engage as early as possible in the WQS development process to ensure adequate time for consideration of any information they provide. The EPA is not establishing a specific process but rather is deferring to existing state processes in place that could serve this purpose, including state public engagement processes that are required for all WQS revisions.

[127] *See* CWA section 303(c)(1).

V. Economic Analysis

Pursuant to Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review), the EPA has prepared an economic analysis to inform the public of potential benefits and costs of this final rule. The EPA's economic analysis is documented in *Economic Analysis for Water Quality Standards Regulatory Revisions to Protect Tribal Reserved Rights (Final Rule)* and can be found in the docket for this final rule.

This final rule does not establish any requirements directly applicable to regulated entities, such as industrial dischargers or municipal wastewater treatment facilities, but could ultimately lead to additional compliance costs to meet permit limits put in place to comply with new WQS adopted by states because of this final rule. Some commenters on the economic analysis that accompanied the EPA's proposed rulemaking asserted that the EPA must estimate costs to regulated entities before finalizing the rule and that many NPDES permits would need to be modified or reissued with more stringent water quality-based effluent limits as a result of this rule. While the EPA has included a qualitative assessment of indirect costs and benefits in the economic analysis that accompanies this final rule, the EPA is unable to quantify indirect costs and benefits since it cannot anticipate precisely how states will implement the rule and because of a lack of data.

While this rule would not directly lead to improvements in water quality, it establishes a framework that, where applicable, is expected to result in future improvements in water quality in geographic areas where Tribes hold reserved rights. Better protection of Tribal reserved rights has the potential to provide a variety of economic benefits associated with cleaner water. The EPA also anticipates that the rule will result in improved coordination between Federal, State, and Tribal governments regarding the protection of water resources that support the exercise of Tribal reserved rights. Tribal

members and the general public may indirectly benefit from this rule through targeted improvements to water quality that are implemented to meet more stringent WQS adopted in accordance with this rule.

The primary benefits of the rule for reserved right holders will likely be improved ability to maintain traditions and cultural landscapes and reduced risk to human health while exercising their reserved rights. Reducing pollutant levels so that traditional foods such as fish and wild rice are abundant and safe to eat in subsistence quantities would allow for unsuppressed levels of Tribal consumption of these resources, which in turn contributes to restoring and maintaining traditional lifeways, preserving Indigenous Knowledge, and cultural self-determination. This rule seeks to ensure that water quality does not limit right holders' ability to exercise their rights, and therefore achieve any corresponding economic, cultural, and social benefits.

Other potential benefits as a result of state actions taken pursuant to this rule include the availability of clean, safe, and affordable drinking water, greater recreational opportunities, water of adequate quality for agricultural and industrial use, and water quality that supports the commercial fishing industry and higher property values. These benefits could accrue to both Tribal and non-Tribal populations.

The EPA acknowledges that achievement of any benefits associated with cleaner water would involve additional control measures, and thus costs to regulated entities and nonpoint sources, that, for the reasons explained above, have not been included in the economic analysis for this rule. The EPA has not attempted to quantify either the costs of control measures that might ultimately be required as a result of state actions taken pursuant to this rule, or the benefits they would provide.

Instead, the focus of the EPA's quantitative analysis of costs is to estimate the potential administrative burden and costs to state and Tribal governments. The EPA does not anticipate this rule would impose any compliance costs on territorial governments because the EPA is not aware of any federally recognized Tribes with reserved rights in any U.S. territory.

The EPA assessed the potential incremental burden and cost of this final rule using the same basic methodology used to assess the potential incremental burden and cost of the EPA's proposed rulemaking. First, the EPA identified the elements of the regulatory revisions that may impose incremental burdens and costs. Then, the EPA estimated the incremental number of labor hours potentially required to comply with those elements of the regulatory revisions, and then estimated the costs associated with those additional labor hours.

The EPA's cost estimate for the final rule is higher than the estimate for the proposed rulemaking for the following reasons:

1. The EPA added estimated costs for all federally recognized Tribes to determine whether they wish to assert their rights for consideration in the WQS context.

2. The EPA increased the estimated labor hours for states in response to comments that the proposed rulemaking underestimated these costs. The EPA made several changes between the proposed and final rule as detailed in this preamble above that the agency anticipates will mitigate the burdens that commenters perceived this rule would impose on states. However, in light of comments received on the additional resources that may be required for activities such as coordinating with right holders to understand the scope and nature of the rights or developing criteria to protect resources that have not been the historic focus of criteria development, the EPA increased its low-end burden estimate five-fold and doubled its high-end burden estimate based on the best professional judgment of EPA staff experienced in the WQS program.

3. The EPA added estimated costs for authorized Tribes to comply with the final rule. The economic analysis for the proposed rulemaking assumed that no authorized Tribes would incur costs as a result of the rule. This was based on the assumption that few, if any Tribes have reserved rights to resources on another Tribe's reservation or otherwise under the jurisdiction of another Tribe, and that if there are Tribes with reserved rights to resources under the jurisdiction of a different Tribe that is an authorized Tribe, their interests may align such that any adopted WQS would reflect consideration and protection of such rights in absence of this rule. In response to comments that these assumptions were not valid, the EPA added estimated costs to account for authorized Tribes who may set WQS for waters where other Tribes hold reserved rights.

4. The EPA updated the labor rates and cost of benefits used in its cost estimates from 2020 to 2022 to reflect the latest available data from the United States Bureau of Labor Statistics (USBLS).

The EPA assumed for the purpose of this analysis that all 574 currently federally recognized Tribes would incur a burden of 10 hours, on average, to evaluate whether they wish to assert their reserved rights in the context of WQS development and, if so, to do so. The EPA also assumed that all 50 states would each undertake three WQS rulemakings to consider and protect Tribal reserved rights. The agency assumed one rulemaking for each of the following purposes:

- To revise WQS for protection of human health;
- To revise WQS for protection of aquatic life; and
- To account for any other WQS changes needed to protect Tribal reserved rights, including addressing the emergence of any information in the future that informs either the applicability of the reserved rights or the necessary level of water quality.

Finally, the EPA assumed that all 84 Tribes currently authorized for treatment in a manner similar to a state for the purpose of establishing WQS (*i.e.,* authorized Tribes) would each undertake two rulemakings to comply with this final rule, one with equivalent burden to the first state rulemaking, and a second rulemaking with 50% less burden than the first.

The EPA has likely over-estimated the incremental burden and costs of this rule. The EPA has included burden and costs for all 574 federally recognized Tribes, all 50 states, and all 84 authorized Tribes, although it is not likely that Tribal reserved rights to aquatic and/or aquatic-dependent resources exist in all 50 states and 84 reservations, nor is it likely that all 574 federally recognized Tribes have relevant reserved rights and will need time to evaluate whether to assert them for consideration in establishment of WQS. Since attributing costs to all currently federally recognized Tribes is likely an overestimate, the EPA anticipates that this estimated burden accounts for any additional Tribes that gain Federal recognition in the foreseeable future, as well as for the fact that some Tribes may incur a higher burden while others incur less or none. For example, some Tribes may elect to incur a higher burden to coordinate with states and authorized Tribes to facilitate a better understanding of the scope and nature of the rights. As a result, the assertion burden estimate should be considered an average value for all federally recognized Tribes.

Further, the EPA also included burden and cost estimates for states and authorized Tribes to consider and revise WQS for protection of aquatic life as a

result of this rule, even though, as explained above in section IV.B.3. of this preamble, this rule is not expected to result in widespread changes to aquatic life criteria. As noted above, in some cases, 40 CFR 131.9(a)(3) may prompt a state to consider adjusting aquatic life criteria in a certain area to protect a culturally important species or to advance the scientific understanding of pollutant impacts to wildlife and plants that have not been the historic focus of criteria development. In addition, states and authorized Tribes may choose to revise designated uses to explicitly denote protection of particular aquatic species to which Tribal reserved rights (as defined in this rule) apply, even if they conclude that existing aquatic life criteria for the relevant water bodies are protective of those species. The EPA included burden and cost related to aquatic life rulemakings to ensure that these burdens, if they occur, would be covered, but including this burden for all 50 states and all 84 authorized Tribes is likely a significant overestimate.

The EPA considered the costs associated with labor from economists, engineers, scientists, and lawyers for development of state and authorized Tribal WQS regulations. The EPA did not include any labor or other costs associated with potential litigation, as this would not be a direct consequence of this rule and would be highly speculative. However, the EPA included costs associated with lawyers in the labor mix in anticipation that legal advice could be needed in evaluating reserved rights.

The EPA anticipates that once a state or authorized Tribe takes into consideration and, where it determines is necessary, adopts new or revised WQS to protect Tribal reserved rights, it will not have any recurring costs (*i.e.,* ongoing annual burden and costs) that would be specifically attributable to the rule revisions to 40 CFR 131.20, because periodic evaluation of and revision to WQS is already a requirement of the CWA and WQS regulation. The EPA also determined that a federally recognized Tribe's evaluation of whether they wish to assert their reserved rights in the context of WQS development was best modeled as a one-time cost, although the right may be asserted in stages.

Estimates of the incremental administrative burden and costs to state and Tribal governments associated with this final rule are summarized in table 2.

TABLE 2—SUMMARY OF POTENTIAL ADMINISTRATIVE BURDENS AND COSTS TO STATE AND TRIBAL GOVERNMENTS ASSOCIATED WITH THE FINAL RULE

Government entity	Burden per entity (hours)	Cost per entity (2022$)	Number of potentially affected entities	Total burden (hours)	Total cost (2022$; one-time)
Federally Recognized Tribes	10	$897.40	574	5740	$515,100
States	1,325–2,650	108,020–216,055	50	66,250–132,500	5,401,000–10,802,000
Authorized Tribes	750–1,500	61,147.50–122,295	84	63,000–126,000	5,136,000–10,272,000
Total				134,990–264,240	11,052,000–21,589,000

Total one-time costs for this final rule are estimated to range from $11,052,000 to $21,589,000. The EPA chose not to annualize these costs given uncertainty about the period over which that annualization would occur.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a ''significant regulatory action'' as defined in Executive Order 12866, as amended by Executive Order 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The EPA prepared an economic analysis of the potential impacts associated with this action. The economic analysis is available in the docket for this action and is summarized in section V of this preamble.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2700.02; OMB assigned control number 2040–0309 when approving the ICR for the proposed rule. A copy of the ICR can be found in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The information collection requirements in this rule will be in addition to the requirements described in the existing ICR for the Water Quality Standards Regulation and approved by OMB through February 2025.[128] At this time, the EPA is not revising the existing ICR to consolidate the requirements of this rule. The EPA will use the information required by this rule to carry out its responsibilities under the CWA to review and approve or disapprove new and revised WQS submitted by states. In reviewing state WQS submissions, the EPA considers whether those submissions are consistent with the WQS regulation at 40 CFR part 131. The existing regulation requires states to include supporting information to accompany WQS submissions to help the EPA determine whether the submitted new and revised WQS are consistent with 40 CFR part 131. This rule adds new requirements to 40 CFR part 131 that holders of Tribal reserved rights must assert their rights in writing to the state and the EPA to receive the benefits of this rule, and that, where applicable, state WQS submissions must include any information provided by right holders about relevant Tribal reserved rights and documentation of how that information was considered. This information collection will provide the EPA with information necessary to review and approve or disapprove WQS in accordance with the CWA and 40 CFR part 131.

[128] ''Information Collection Request for Water Quality Standards Regulation,'' OMB Control Number 2040–0049, EPA ICR Number 0988.15, expiration date February 28, 2025.

If the information collection activities in this rule are not carried out, states and the EPA may not be able to ensure that WQS are consistent with treaties and other Federal laws. In some cases, this could result in implementation steps such as TMDLs and NPDES permits that also are not consistent with treaties and other Federal laws.

Respondents/affected entities: states, federally recognized Tribes, and Tribes authorized for treatment in a manner similar to a state for purposes of establishing WQS under the CWA.

Respondent's obligation to respond: mandatory under 40 CFR part 131 for states and authorized Tribes in their capacity of establishing WQS; for all federally recognized Tribes, required to obtain the benefit of having their rights considered under 40 CFR part 131.

Estimated number of respondents: 624 (84 of which are both federally recognized Tribes and Tribes authorized for treatment in a manner similar to a state for purposes of establishing WQS under the CWA).

Frequency of response: on occasion/as necessary.

Total estimated burden: 20,000 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1.63 million (per year), includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. In making this determination, the EPA concludes that the impact of concern is any significant adverse economic impact on small entities and that the agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because small entities are not directly regulated by this rule and this action will not impose any requirements on small entities; rather, this action will impose requirements only on states to take into consideration whether and how WQS may need to be revised in accordance with 40 CFR 131.9(a).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

The EPA has concluded that this action does not have federalism implications as defined by the EPA's policy for implementing E.O. 13132 [129] on federalism. This rule does not impose substantial compliance costs on state and local governments or on small governments or preempt state or local laws. As explained above, this rule establishes the EPA's expectations for states in setting WQS where Tribal reserved rights apply. This rule adds new requirements that are applicable in certain instances, *i.e.,* where right holders assert relevant Tribal reserved rights consistent with 40 CFR 131.9, and which build on and are consistent with the EPA's existing WQS paradigm at 40 CFR part 131. The requirement to have criteria that protect the designated use is an existing requirement, and the states maintain their role in designating uses. States continue to have considerable discretion in adopting and implementing WQS. This rule will not have substantial direct effects [130] on the states, on the relationship between the Federal Government and the states, or on the distribution of power and responsibilities among the various levels of government. Thus, E.O. 13132 does not apply to this action.

In the spirit of E.O. 13132 and consistent with the EPA's policy to promote communications between the EPA and state and local governments, in January 2023, the EPA presented an overview of the proposed rulemaking to the Association of Clean Water Administrators (ACWA)'s Monitoring, Standards and Assessment Subcommittee. The EPA provided additional engagement during three additional meetings with ACWA representatives in 2023 at their request to hear their views on implementation of this rule in addition to accepting written comments on the proposal.

Written comments on the proposed rulemaking were submitted by 13 state governments, including state environmental agencies, water boards, governors' offices, and attorneys general. Comments were also submitted by national and regional state associations. The EPA summarized and responded in detail to public comment letters from state governments and associations in a Response to Comments document that can be found in the docket for this rule.

Participants reiterated concerns raised in their comment letters, including that the EPA did not provide sufficient engagement with states in shaping the proposed rulemaking. The EPA provided states with the same opportunities for engagement provided to the general public plus additional dedicated meetings. In addition, the EPA has carefully considered the states' comments and in some instances has made changes to the proposed rulemaking language in this final rule that may mitigate the states' concerns. These changes are detailed in relevant sections of this preamble.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has Tribal implications, however it will neither impose substantial direct compliance costs on federally recognized Tribal governments, nor preempt Tribal law. This rule may affect Tribes with reserved rights to aquatic and/or aquatic-dependent resources in waters subject to state WQS, and it may also affect Tribes administering a CWA section 303(c) WQS program. To date, 84 Indian Tribes have been approved for treatment in a manner similar to a state (TAS) for CWA sections 303(c) and 401.[131] Some of these authorized Tribes could be subject to this final rule, depending on the location and nature of any other Tribes' rights.

The EPA consulted with Tribal officials early in the process of developing this regulation to permit

[129] E.O. 13132 requires meaningful and timely consultation with elected state and local officials or their representative national organizations early in the process of developing the proposed regulation. Under the technical requirements of E.O. 13132, agencies must conduct a federalism consultation as outlined in the Executive order for regulations that (1) have federalism implications, that impose substantial direct compliance costs on state and local governments, and that are not required by statute; or (2) that have federalism implications and that preempt state law. Where actions are determined to have federalism implications as defined by agency policy for implementing E.O. 13132, a federalism summary impact statement is published in the preamble to the regulation, and the agencies must provide OMB copies of all written communications submitted by state and local officials.

[130] *i.e.,* imposed intergovernmental costs or preemption of state/local law.

[131] To date, one Tribe with TAS for CWA section 303(c) (Havasupai Tribe in Arizona) has declined TAS for CWA section 401. For the most current information please refer to *https://www.epa.gov/wqs-tech/epa-actions-tribal-water-quality-standards-and-contacts.*

them to have meaningful and timely input into its development. The EPA held a 90-day pre-proposal Tribal consultation and coordination period from June 15 through September 13, 2021, to inform development of the proposed rulemaking. The EPA conducted the consultation and coordination process in accordance with the EPA Policy on Consultation and Coordination with Indian Tribes in effect at the time.[132] In addition to two national Tribal listening sessions held in July and August 2021, the EPA presented at 20 meetings of Tribal staff and leadership, as well as held seven staff-level coordination meetings and seven leader-to-leader meetings at the request of Tribes. The EPA continued outreach and engagement with Tribes at national and regional Tribal meetings after the end of the consultation period before publishing the proposed rulemaking. Twenty-one Tribes and Tribal organizations submitted written pre-proposal comments to the EPA. These are included in the docket for the rule.

The EPA held a second 90-day Tribal consultation and coordination period after the Administrator signed the proposed rulemaking from November 30, 2022, to February 28, 2023. During the second Tribal consultation and coordination period and throughout the public comment period, the EPA held two additional national listening sessions for Tribal representatives, in January 2023, as well as seven leader-to-leader meetings and twelve staff-level coordination meetings with representatives of individual Tribes upon request. A summary of the EPA's Tribal consultation titled *Summary Report of Tribal Consultation on Revisions to the Federal Water Quality Standards Regulation to Protect Tribal Reserved Rights* is available in the docket for this rule.

The EPA encouraged Tribal representatives to submit written comments through the docket on the proposed rulemaking. The EPA received written comments representing 47 Tribes and Tribal organizations raising a wide variety of complex questions and concerns, which largely captured the questions and concerns Tribes raised during consultation and engagement meetings. Key themes included how Tribal interests and sensitive information will be protected, how disputes will be resolved, and numerous specific recommendations for expanding the inclusiveness and protectiveness of the rule. The EPA carefully considered all Tribal comments in development of the final rule and made several clarifications in the preamble to this final rule and changes in response to comments on the proposed regulation to address Tribal concerns. The EPA has responded in detail to Tribal comments along with other public comments received in the Response to Comment document available in the docket for this rule. In addition, the EPA has continued to engage with Tribes to discuss their water quality concerns, including concerns centered on reserved rights and protection of subsistence fishing, in a variety of forums, including regular meetings and discussions with the National Tribal Water Council.[133]

As required by section 7(a), the EPA's Designated Consultation Official has certified that the requirements of the Executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. 40 CFR 131.9(a) will be relevant to protection of human health in situations where it is applied to establishing WQS to protect human health. It is not possible to evaluate whether this provision would result in disproportionate risks on children in any given case since the EPA lacks information about every instance where the rule will be applied. However, in general, the EPA recommends that human health criteria be designed to reduce the risk of adverse cancer and non-cancer effects occurring from a lifetime of exposure to pollutants through the ingestion of drinking water and consumption of fish/shellfish obtained from inland and nearshore waters. Any human health criteria established pursuant to this regulation would similarly be based on reducing the chronic health effects occurring from lifetime exposure and therefore are expected to be protective of a person's exposure during both childhood and adult years.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action impacts state and Tribal water quality standards, which do not regulate the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

This rule does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns. The failure to consider and protect Tribal reserved rights in WQS may contribute to suppression effects that can negatively impact the health, culture, and economy of Indigenous peoples. These impacts may be further exacerbated by climate change, resulting in cumulative disproportionate and adverse effects on the health and environment of Indigenous peoples. As mentioned in section V of this preamble above and more fully explained in the economic analysis for the final rule, which is available in the docket for this rule, the EPA was unable to quantify disproportionate and adverse impacts of the existing condition prior to this rule because the EPA does not have complete data about where Tribal reserved rights exist and where existing WQS do and do not protect those rights. Instead, below the EPA has qualitatively assessed the disproportionate and adverse impacts of the existing condition prior to this rule. This assessment was conducted to inform the

[132] USEPA, 2011. EPA Policy on Consultation and Coordination with Indian Tribes.

[133] The National Tribal Water Council (NTWC) is a technical and scientific body created to assist the EPA; federally recognized Indian Tribes, including Alaska Native Tribes; and their associated Tribal communities and Tribal organizations with research and information for decision-making regarding water issues and water-related concerns that affect Indian and Alaska Native Tribal members, as well as other residents of Alaska Native Villages and Indian country in the United States.

EPA's understanding of the benefits of the rule.

Many Tribes in the U.S. rely on subsistence fishing or otherwise have reserved rights to use aquatic and aquatic-dependent resources in ways that differ from how the U.S. general population uses these resources, and/or have rights to harvest such resources at relatively higher rates than the general population. As a result, in some parts of the country, WQS that may sufficiently protect the general population may not be sufficiently stringent and/or comprehensive to protect Tribes exercising their reserved rights. These rights often reflect traditional practices that support a Tribe's cultural self-determination and can be pivotal to the economic well-being of the community. Impacts to these rights can affect the very foundation of Tribal social and political organization [134] as well as a Tribe's ability to provide for present and future generations and the maintenance of their lifeways.

For example, some Tribes have rights to fish for subsistence, which typically implies a higher rate of fish consumption than that at which the general population consumes fish from U.S. waters. The fish consumption rate is a key input to the equation used to calculate water quality criteria to protect human health; [135] such criteria represent the maximum levels of contaminants that can be present in waters for the fish caught in those waters to be safe to eat at the given rate. If all other inputs to the human health criteria equation remain the same, increasing the fish consumption rate results in more stringent criteria. For subsistence fishers, the EPA recommends a default fish consumption rate of 142 g/day in the absence of local data.[136] This rate is the estimated 99th percentile fish consumption rate from the 1994–96 Continuing Survey of Food Intake by Individuals (CSFII) conducted by the U.S. Department of Agriculture.[137] The EPA's 2000 Methodology noted that at the time 142 g/day was ''representative of average rates for highly exposed groups such as subsistence fishermen, specific ethnic groups, or other highly exposed people.'' [138] Post-2000 consumption surveys of high fish consuming populations (*e.g.,* Tribes and Asian Pacific Islanders) resulted in mean fish consumption rates ranging from 18.6 g/day to 233 g/day and 90th percentile fish consumption rates ranging from 48.9 g/day to 528 g/day.[139]

In contrast, states generally rely on the EPA's nationally recommended default fish consumption rate for the general population to calculate their human health criteria. The EPA's current nationally recommended default fish consumption rate is 22 g/day, which represents the 90th percentile consumption rate of fish and shellfish from inland and nearshore waters for the U.S. adult population 21 years of age and older, based on National Health and Nutrient Examination Survey (NHANES) data from 2003 to 2010.[140] Some states rely on this current national default fish consumption rate to calculate their statewide human health criteria, and many others have not updated their human health criteria since 2015 and rely on the EPA's prior, outdated default general population fish consumption rates (17.5 g/day or 6.5 g/day), which results in less stringent human health criteria. In states that rely on current or outdated national default general population fish consumption rates, for waters in which Tribes have rights to fish for subsistence, the existing human health criteria may expose Tribal members exercising their legal rights to consume higher amounts of fish to greater risk from toxic pollutants. The rule will have the benefit of ensuring that criteria are set at appropriate levels to protect the exercise of Tribal reserved rights.

Additionally, the EPA's current guidance for developing human health criteria [141] does not address how Tribal populations with reserved rights should be treated in developing human health criteria. Some states have treated Tribal populations as high consuming subpopulations. Since the 2000 Methodology is not specific about how to treat Tribal populations with reserved rights, it could be read as implying those Tribal populations could be protected at a less stringent cancer risk level of 10^{-4} as compared to the general population, for which the EPA recommends 10^{-5} or 10^{-6}. This regulation clarifies this important point on which the EPA's current guidance is silent.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with environmental justice concerns. Specifically, one benefit of this action is to directly address existing disproportionate and adverse effects of state WQS that fail to protect Tribal reserved rights by requiring states to consider Tribal reserved rights in establishing their WQS and requiring states to protect Tribal populations to the same risk level to which the general population of the state would otherwise be protected. This action makes the EPA's regulation explicit about how states are to consider Tribal reserved rights in adopting and revising WQS.

Finally, as discussed in section IV.F of this preamble, this rule establishes explicit regulatory requirements to provide right holders with meaningful opportunities to engage during the WQS development process. Specifically, the final rule requires state WQS submissions to include as supporting information any information provided by the right holders. This will encourage

[134] Ranco, D.J., O'Neill, C.A., Donatuto, J., & Harper, B.L. 2011. Environmental Justice, American Indians and the Cultural Dilemma: Developing Environmental Management for Tribal Health and Well-being. *Environmental Justice* 4;4, DOI: *10.1089/env.2010.0036.*

[135] USEPA. (2000). *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.*

[136] *Id.* at 1–13.

[137] Jacobs, H.L., Kahn, H.D., Stralka, K.A., and Phan, D.B. (1998). *Estimates of per capita fish consumption in the U.S. based on the continuing survey of food intake by individuals (CSFII).* Risk Analysis: An International Journal 18(3).

[138] USEPA. (2000). *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health.* EPA–822–B–00–004. *https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf* at 4–27.

[139] Polissar, N.L., Salisbury, A., Ridolfi, C., Callahan, K., Neradilek, M., Hippe, D.S., and Beckley, W.H. (2016). *A Fish Consumption Survey of the Nez Perce Tribe.* The Mountain-Whisper-Light Statistics, Pacific Market Research, Ridolfi, Inc. *https://www.epa.gov/sites/production/files/2017-01/documents/fish-consumption-survey-nez-perce-dec2016.pdf;* Polissar, N.L., Salisbury, A., Ridolfi, C., Callahan, K., Neradilek, M., Hippe, D.S., and W.H. Beckley. (2016). *A Fish Consumption Survey of the Shoshone-Bannock Tribes.* The Mountain-Whisper-Light Statistics, Pacific Market Research, Ridolfi, Inc. *https://www.epa.gov/sites/production/files/2017-01/documents/fish-consumption-survey-shoshone-bannock-dec2016.pdf;* Seldovia Village Tribe. (2013). *Assessment of Cook Inlet Tribes Subsistence Consumption.* Seldovia Village Tribe Environmental Department; Suquamish Tribe. (2000). *Fish Consumption Survey of The Suquamish Indian Tribe of The Port Madison Indian Reservation, Puget Sound Region.* Suquamish, W.A.; Sechena, R., Liao, S., Lorenzana, R., Nakano, C., Polissar, N., Fenske., R. (2003). *Asian American and Pacific Islander seafood consumption—a community-based study in King County, Washington.* J of Exposure Analysis and Environ Epidemiology. (13): 256–266; Lance, T.A., Brown, K., Drabek, K., Krueger, K., and S. Hales. (2019). *Kodiak Tribes Seafood Consumption Assessment: Draft Final Report,* Sun'aq Tribe of Kodiak, Kodiak, AK. *http://sunaq.org/wp-content/uploads/2016/09/Kodiak-Tribes-Seafood-Consumption-Assessment-DRAFT-Final-Report-26Feb19-FINAL.pdf.*

[140] USEPA. (2014). *Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations* (NHANES 2003–2010). EPA 820–R–14–002. *https://www.epa.gov/sites/default/files/2015-01/documents/fish-consumption-rates-2014.pdf.*

[141] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, DC EPA–822–B–00–004. *https://www.epa.gov/wqc/human-health-water-quality-criteria-and-methods-toxics.*

states to meaningfully engage Tribes in WQS development, although states retain discretion on how and when to engage. Consistent with applicable EPA Tribal consultation policies, the final rule also requires the EPA to offer consultation to Tribes when the EPA is evaluating state WQS submissions that impact Tribal reserved rights that the right holder has asserted for consideration in the WQS context. These new regulatory requirements recognize the importance of State and Federal coordination with Tribes by establishing mechanisms for Tribal input in the WQS setting process.

A few comments the EPA received on the proposed rulemaking also asserted that a legacy of and ongoing environmental injustices imposes disproportionate health risks on Tribal communities throughout the U.S., and that this rule is important for advancing environmental justice and protecting vulnerable communities from climate change.

For the reasons explained in section V of this preamble above and as more fully explained in the economic analysis for this final rule, which is available in the docket for this rule, the EPA is unable to quantify the anticipated reduction in disproportionate and adverse effects to Tribal populations that will result from this final rule. This revision to the Federal WQS regulation is not self-implementing. It establishes rules for states and will be implemented by states revising their WQS. While the EPA is aware of particular situations in certain parts of the country in which Tribal reserved rights have previously been identified in relation to water quality issues, the EPA cannot estimate with certainty the geographic distribution of Tribal reserved rights across the country and how those rights apply to various CWA-protected aquatic and/or aquatic-dependent resources, which of those rights Tribes would choose to assert for consideration in establishment of WQS, whether and how states may revise various WQS components to protect the asserted rights, or how the scope or stringency of any state WQS will change as a result.

The EPA additionally identified and addressed environmental justice concerns by maximizing opportunities for meaningful involvement of Tribal governments in providing input on the rulemaking through both pre- and post-proposal Tribal consultation, as explained in section VI.F. of this preamble above.

The information supporting this Executive order review is contained in the above preamble, the document titled *Summary Report of Tribal Consultation on Revisions to the Federal Water Quality Standards Regulation to Protect Tribal Reserved Rights* and the Economic Analysis for this final rule. The latter two documents can be found in the docket for this rule.

The EPA recognizes that Tribes without federally reserved rights to aquatic or aquatic-dependent resources will not be directly impacted by this rule. The agency also acknowledges that since this rule only covers locations with reserved rights, other aquatic resources upon which Tribes depend may not be covered. It is the EPA's expectation that many of the coordination and collaboration processes that will be developed to implement this rule will also lead to better protection of aquatic and aquatic-dependent resources not referenced in treaties and similar instruments because this rulemaking aims to facilitate greater coordination between the EPA, states, and Tribal governments. The EPA will continue to work with states and Tribes to help reach this goal. While this rule does not address all obstacles to the full exercise of Tribal reserved rights, the EPA believes it takes a positive step in that direction.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 131

Environmental protection, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart A—General Provisions

■ 2. Amend § 131.3 by adding paragraphs (r) and (s) to read as follows:

§ 131.3 Definitions.

* * * * *

(r) *Tribal reserved rights,* for purposes of this part, are any rights to CWA-protected aquatic and/or aquatic-dependent resources reserved by right holders, either expressly or implicitly, through Federal treaties, statutes, or Executive orders.

(s) *Right holders,* for purposes of this part, are any Federally recognized Tribes holding Tribal reserved rights, regardless of whether the Tribe exercises authority over a Federal Indian reservation.

■ 3. Amend § 131.5 by adding paragraph (a)(9) and revising paragraph (b) to read as follows:

§ 131.5 EPA authority.

(a) * * *

(9) Where applicable, whether State adopted water quality standards are consistent with § 131.9.

(b) If EPA determines that the State's or Tribe's water quality standards are consistent with the factors listed in paragraphs (a)(1) through (9) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (9) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *

■ 4. Amend § 131.6 by adding paragraph (g) to read as follows:

§ 131.6 Minimum requirements for water quality standards submission.

* * * * *

(g) Where applicable, information that will aid the Agency in evaluating whether the submission is consistent with § 131.9, including:

(1) Any information provided by right holders about relevant Tribal reserved rights and documentation of how that information was considered; and

(2) Data and methods used to develop the water quality standards.

Subpart B—Establishment of Water Quality Standards

■ 5. Add § 131.9 to subpart B to read as follows:

§ 131.9 Protection of Tribal reserved rights.

(a) Where a right holder has asserted a Tribal reserved right in writing to the State and EPA for consideration in establishment of water quality standards, to the extent supported by available data and information, the State must:

(1) Take into consideration the use and value of their waters for protecting

the Tribal reserved right in adopting or revising designated uses pursuant to § 131.10;

(2) Take into consideration the anticipated future exercise of the Tribal reserved right unsuppressed by water quality in establishing relevant water quality standards; and

(3) Establish water quality criteria, consistent with § 131.11, to protect the Tribal reserved right where the State has adopted designated uses that either expressly incorporate protection of or encompass the right. This requirement includes developing criteria to protect right holders using at least the same risk level (*e.g.,* cancer risk level, hazard quotient, or illness rate) as the State would otherwise use to develop criteria to protect the State's general population, paired with exposure inputs (*e.g.,* fish consumption rate) representative of right holders exercising their reserved right.

(b) States and right holders may request EPA assistance with evaluating Tribal reserved rights. EPA will provide such assistance to the extent practicable. In providing assistance to States as they adopt and revise water quality standards consistent with paragraph (a) of this section, EPA will engage with right holders.

(c) In reviewing State water quality standards submissions under this section, EPA will initiate the Tribal consultation process with the right holders that have asserted their rights for consideration in establishment of water quality standards, consistent with applicable EPA Tribal consultation policies, in determining whether State water quality standards are consistent with paragraph (a) of this section.

Subpart C—Procedures for Review and Revision of Water Quality Standards

■ 6. Amend § 131.20 by revising paragraph (a) to read as follows:

§ 131.20 State review and revision of water quality standards.

(a) *State review.* The State shall from time to time, but at least once every 3 years, hold public hearings for the purpose of reviewing applicable water quality standards adopted pursuant to §§ 131.9 through 131.15 and Federally promulgated water quality standards and, as appropriate, modifying and adopting standards. This review shall include evaluating whether there is any new information available about Tribal reserved rights applicable to State waters that needs to be considered to establish water quality standards consistent with § 131.9. The State shall also re-examine any waterbody segment with water quality standards that do not include the uses specified in section 101(a)(2) of the Act every 3 years to determine if any new information has become available. If such new information indicates that the uses specified in section 101(a)(2) of the Act are attainable, the State shall revise its standards accordingly. Procedures States establish for identifying and reviewing water bodies for review should be incorporated into their Continuing Planning Process. In addition, if a State does not adopt new or revised criteria for parameters for which EPA has published new or updated CWA section 304(a) criteria recommendations, then the State shall provide an explanation when it submits the results of its triennial review to the Regional Administrator consistent with CWA section 303(c)(1) and the requirements of paragraph (c) of this section.

* * * * *

[FR Doc. 2024–09427 Filed 5–1–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA–HQ–TRI–2022–0262; FRL–2425.1–05–OCSPP]

RIN 2025–AA17

Addition of Diisononyl Phthalate Category; Community Right-to-Know Toxic Chemical Release Reporting; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendment.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is correcting a final rule that appeared in the **Federal Register** on July 14, 2023, which added a diisononyl phthalates (DINP) category to the list of toxic chemicals subject to the reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Pollution Prevention Act (PPA). However, the amendment could not be incorporated into the regulation due to an inaccurate amendatory instruction. This document corrects the amendatory instructions.

DATES: Effective on May 2, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–TRI–2022–0262, is available at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Rachel Dean, Data Collection Branch, Data Gathering, Management, and Policy Division (Mail code: 7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1303; email address: *dean.rachel@epa.gov.*

For general information contact: The Emergency Planning and Community Right-to-Know Information Center; telephone number: (800) 424–9346 or (703) 348–5070 in the Washington, DC Area and International; website: *https://www.epa.gov//hotlines.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

The Agency included in the July 14, 2023, final rule a list of those who may be potentially affected by this action.

II. What does this correction do?

EPA issued a final rule in the **Federal Register** on July 14, 2023 (88 FR 45089) (FRL–2425.1–03–OCSPP) which added a diisononyl phthalates (DINP) category to the list of toxic chemicals subject to the reporting requirements under the EPCRA and the PPA. In the final rule's instructions to amend the Code of Federal Regulations (CFR), EPA intended to add the DINP category alphabetically to the list of TRI chemical categories at 40 CFR 372.65(c). However, the list of TRI chemical categories in the CFR at the time had been incorporated as a static image of a table, which introduced formatting challenges with regard to updating 40 CFR 372.65(c) per the amendatory instructions in the DINP category rule because the Agency did not provide a new static image of the table. This document corrects the formatting in Table 3 to paragraph (c) of 40 CFR 372.65(c) by removing the static image of the table and replacing it with a table consisting of text and images of chemicals structures, as applicable.

III. Why is this correction issued as a final rule?

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(3)(B)) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that notice and public

procedure are unnecessary because EPA provided a full opportunity for notice and comment before issuing the final rule that published in the **Federal Register** on July 14, 2023, and this correction merely corrects the amendatory instructions to ensure that the rule is correctly codified in the CFR. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(3)(B).

IV. Do any of the statutory and executive order review requirements apply to this action?

No. For a detailed discussion concerning the statutory and executive order review requirements refer to Unit VI. of the final rule issued on July 14, 2023.

V. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: April 24, 2024.

Michal Freedhoff

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, EPA is amending 40 CFR part 372 as follows:

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

■ 1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

■ 2. In § 372.65, amend Table 3 in paragraph (c) to read as follows:

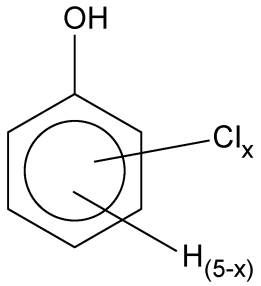
§ 372.65 Chemicals and chemical categories to which this part applies.

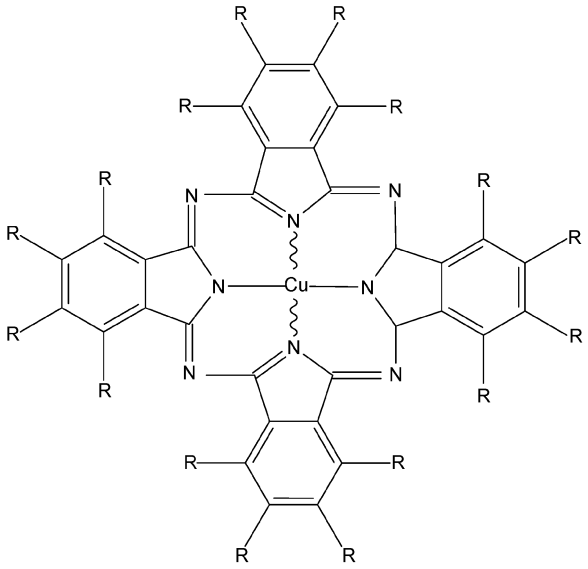
* * * * *

(c) * * *

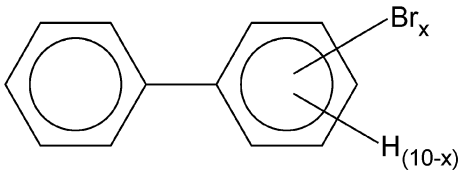
Table 3 to Paragraph (c)

BILLING CODE 6560–50–P

Category name	Effective Date
Antimony compounds: Includes any unique chemical substance that contains antimony as part of that chemical's infrastructure.	1/1/1987
Arsenic compounds: Includes any unique chemical substance that contains arsenic as part of that chemical's infrastructure.	1/1/1987
Barium compounds: Includes any unique chemical substance that contains barium as part of that chemical's infrastructure (except for barium sulfate (CAS No. 7727-43-7)).	1/1/1987
Beryllium compounds: Includes any unique chemical substance that contains beryllium as part of that chemical's infrastructure.	1/1/1987
Cadmium compounds: Includes any unique chemical substance that contains cadmium as part of that chemical's infrastructure.	1/1/1987
Certain glycol ethers $R\text{-}(OCH_2CH_2)_n\text{-}OR'$ Where: n = 1, 2, or 3; R = alkyl C7 or less; or R = phenyl or alkyl substituted phenyl; R′ = H or alkyl C7 or less; or OR′ consisting of carboxylic acid ester, sulfate, phosphate, nitrate, or sulfonate.	1/1/1995
Chlorophenols  Where x = 1 to 5	1/1/1987
Chromium compounds: Includes any unique chemical substance that contains chromium as part of that chemical's infrastructure (except for chromite ore mined in the Transvaal Region of South Africa and the unreacted ore component of the chromite ore processing residue (COPR). COPR is the solid waste remaining after aqueous extraction of oxidized chromite ore that has been combined with soda ash and kiln roasted at approximately 2,000 °F).	1/1/1987
Cobalt compounds: Includes any unique chemical substance that contains cobalt as part of that chemical's infrastructure.	1/1/1987

Copper compounds: Includes any unique chemical substance that contains copper as part of that chemical's infrastructure (except for C.I. Pigment Blue 15 (PB-15, CAS No. 147-14-8), C.I. Pigment Green 7 (PG-7, CAS No. 1328-53-6), and C.I. Pigment Green 36 (PG-36, CAS No. 14302-13-7)) and except copper phthalocyanine compounds that are substituted with only hydrogen and/or bromine and/or chlorine that meet the following molecular structure definition:  Where R = H and/or Br and/or Cl only.	1/1/1987
Cyanide compounds: X^+CN^- where X^+ = any group (except H^+) where a formal dissociation can be made. For example, KCN or $Ca(CN)_2$.	1/1/1987
Diisocyanates (This category includes only those chemicals listed below) 38661-72-2 1,3-Bis(methylisocyanate)cyclohexane 10347-54-3 1,4-Bis(methylisocyanate)cyclohexane (1,4-Bis(isocyanatomethyl)cyclohexane) 2556-36-7 1,4-Cyclohexane diisocyanate 134190-37-7 Diethyldiisocyanatobenzene 4128-73-8 4,4'-Diisocyanatodiphenyl ether 75790-87-3 2,4'-Diisocyanatodiphenyl sulfide 91-93-0 3,3'-Dimethoxybenzidine-4,4'-diisocyanate 91-97-4 3,3'-Dimethyl-4,4'-diphenylene diisocyanate 139-25-3 3,3'-Dimethyldiphenylmethane-4,4'-diisocyanate 822-06-0 Hexamethylene-1,6-diisocyanate 4098-71-9 Isophorone diisocyanate 75790-84-0 4-Methyldiphenylmethane-3,4-diisocyanate 5124-30-1 1,1-Methylene bis(4-isocyanatocyclohexane) 101-68-8 4,4'-Methylenedi(phenyl isocyanate) 3173-72-6 1,5-Naphthalene diisocyanate 123-61-5 1,3-Phenylene diisocyanate 104-49-4 1,4-Phenylene diisocyanate 9016-87-9 Polymeric diphenylmethane diisocyanate 16938-22-0 2,2,4-Trimethylhexamethylene diisocyanate 15646-96-5 2,4,4-Trimethylhexamethylene diisocyanate	1/1/1995

Diisononyl Phthalates (DINP): Includes branched alkyl di-esters of 1,2 benzenedicarboxylic acid in which alkyl ester moieties contain a total of nine carbons. (This category includes but is not limited to the chemicals covered by the CAS numbers and names listed here). 28553-12-0 Diisononyl phthalate 71549-78-5 Branched dinonyl phthalate 14103-61-8 Bis(3,5,5-trimethylhexyl) phthalate 68515-48-0 Di(C8-10, C9 rich) branched alkyl phthalates 20548-62-3 Bis(7-methyloctyl) phthalate 111983-10-9 Bis(3-ethylheptan-2-yl) benzene-1,2-dicarboxylate	1/1/2024
Dioxin and dioxin-like compounds (Manufacturing; and the processing or otherwise use of dioxin and dioxin like compounds if the dioxin and dioxin like compounds are present as contaminants in a chemical and if they were created during the manufacturing of that chemical.) (This category includes only those chemicals listed below). 67562-39-4 1,2,3,4,6,7,8-Heptachlorodibenzofuran 55673-89-7 1,2,3,4,7,8,9-Heptachlorodibenzofuran 35822-46-9 1,2,3,4,6,7,8-Heptachlorodibenzo-*p*-dioxin 39227-28-6 1,2,3,4,7,8-Hexachlorodibenzo-*p*-dioxin 57653-85-7 1,2,3,6,7,8-Hexachlorodibenzo-*p*-dioxin 19408-74-3 1,2,3,7,8,9-Hexachlorodibenzo-*p*-dioxin 70648-26-9 1,2,3,4,7,8-Hexachlorodibenzofuran 57117-44-9 1,2,3,6,7,8-Hexachlorodibenzofuran 72918-21-9 1,2,3,7,8,9-Hexachlorodibenzofuran 60851-34-5 2,3,4,6,7,8-Hexachlorodibenzofuran 39001-02-0 1,2,3,4,6,7,8,9-Octachlorodibenzofuran 3268-87-9 1,2,3,4,6,7,8,9-Octachlorodibenzo-*p*-dioxin 57117-41-6 1,2,3,7,8-Pentachlorodibenzofuran 57117-31-4 2,3,4,7,8-Pentachlorodibenzofuran 40321-76-4 1,2,3,7,8-Pentachlorodibenzo-*p*-dioxin 51207-31-9 2,3,7,8-Tetrachlorodibenzofuran 1746-01-6 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin	1/1/2000
Ethylenebisdithiocarbamic acid, salts and esters.	1/1/1994
Hexabromocyclododecane (This category includes only those chemicals covered by the CAS numbers listed here) 3194-55-6 1,2,5,6,9,10-Hexabromocyclododecane 25637-99-4 Hexabromocyclododecane	1/1/2017
Lead compounds: Includes any unique chemical substance that contains lead as part of that chemical's infrastructure.	1/1/1987
Manganese compounds: Includes any unique chemical substance that contains manganese as part of that chemical's infrastructure.	1/1/1987
Mercury compounds: Includes any unique chemical substance that contains mercury as part of that chemical's infrastructure.	1/1/1987
Nickel compounds: Includes any unique chemical substance that contains nickel as part of that chemical's infrastructure.	1/1/1987
Nicotine and salts.	1/1/1995
Nitrate compounds (water dissociable; reportable only when in aqueous solution).	1/1/1995

Nonylphenol (This category includes only those chemicals listed below). 104-40-5 4-Nonylphenol (*p*-Nonylphenol) 11066-49-2 Isononylphenol 25154-52-3 Nonylphenol 26543-97-5 4-Isononylphenol 84852-15-3 4-Nonylphenol, branched (Branched *p*-nonylphenol) 90481-04-2 Nonylphenol, branched	1/1/2015
Nonylphenol Ethoxylates (This category includes only those chemicals covered by the CAS numbers listed here). 7311-27-5 Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]ethoxy]- 9016-45-9 Poly(oxy-1,2-ethanediyl), α-(nonylphenyl)-ω-hydroxy-; (Polyethylene glycol nonylphenyl ether) 20427-84-3 Ethanol, 2-[2-(4-nonylphenoxy)ethoxy]-; (2-[2-(4-Nonylphenoxy)ethoxy]ethanol) 26027-38-3 Poly(oxy-1,2-ethanediyl), α-(4-nonylphenyl)-ω-hydroxy-; (*p*-Nonylphenol polyethylene glycol ether) 26571-11-9 3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(nonylphenoxy)- 27176-93-8 Ethanol, 2-[2-(nonylphenoxy)ethoxy]-; (Diethylene glycol nonylphenol ether) 27177-05-5 3,6,9,12,15,18,21-Heptaoxatricosan-1-ol, 23-(nonylphenoxy)- 27177-08-8 3,6,9,12,15,18,21,24,27-Nonaoxanonacosan-1-ol, 29-(nonylphenoxy)- 27986-36-3 Ethanol, 2-(nonylphenoxy)-; (2-(Nonylphenoxy)ethanol) 37205-87-1 Poly(oxy-1,2-ethanediyl), α-(isononylphenyl)-ω-hydroxy- 51938-25-1 Poly(oxy-1,2-ethanediyl), α-(2-nonylphenyl)-ω-hydroxy- 68412-54-4 Poly(oxy-1,2-ethanediyl), α-(nonylphenyl)-ω-hydroxy-, branched; (Polyethylene glycol mono(branched nonylphenyl) ether) 127087-87-0 Poly(oxy-1,2-ethanediyl), α-(4-nonylphenyl)-ω-hydroxy-, branched; (Polyethylene glycol mono(branched *p*-nonylphenyl) ether)	1/1/2019
Polybrominated biphenyls (PBBs)  Where x = 1 to 10	1/1/1987
Polychlorinated alkanes (C_{10} to C_{13}): Includes those chemicals defined by the following formula: $C_xH_{2x-y+2}Cl_y$ where x = 10 to 13; y = 3 to 12; and where the average chlorine content ranges from 40-70% with the limiting molecular formulas $C_{10}H_{19}Cl_3$ and $C_{13}H_{16}Cl_{12}$	1/1/1995

Polycyclic aromatic compounds (PACs): (This category includes only those chemicals listed below).	1/1/1995
56-55-3 Benz[a]anthracene	
218-01-9 Benzo[a]phenanthrene (Chrysene)	
50-32-8 Benzo[a]pyrene	
205-99-2 Benzo[b]fluoranthene	
205-82-3 Benzo[j]fluoranthene	
207-08-9 Benzo[k]fluoranthene	
206-44-0 Benzo[j,k]fluorene (Fluoranthene)	1/1/2000
189-55-9 Benzo[r,s,t]pentaphene (Dibenzo[a,i]pyrene)	
226-36-8 Dibenz[a,h]acridine	
224-42-0 Dibenz[a,j]acridine	
53-70-3 Dibenzo[a,h]anthracene (Dibenz[a,h]anthracene)	
5385-75-1 Dibenzo[a,e]fluoranthene	
192-65-4 Dibenzo[a,e]pyrene	
189-64-0 Dibenzo[a,h]pyrene	
191-30-0 Dibenzo[a,l]pyrene	
194-59-2 7H-Dibenzo[c,g]carbazole	
57-97-6 7,12-Dimethylbenz[a]anthracene	
42397-64-8 1,6-Dinitropyrene	1/1/2011
42397-65-9 1,8-Dinitropyrene	1/1/2011
193-39-5 Indeno[1,2,3-cd]pyrene	
56-49-5 3-Methylcholanthrene	1/1/2000
3697-24-3 5-Methylchrysene	
7496-02-8 6-Nitrochrysene	1/1/2011
5522-43-0 1-Nitropyrene	
57835-92-4 4-Nitropyrene	1/1/2011
Selenium compounds: Includes any unique chemical substance that contains selenium as part of that chemical's infrastructure.	1/1/1987
Silver compounds: Includes any unique chemical substance that contains silver as part of that chemical's infrastructure.	1/1/1987
Strychnine and salts.	1/1/1995
Thallium compounds: Includes any unique chemical substance that contains thallium as part of that chemical's infrastructure.	1/1/1987
Vanadium compounds.	1/1/2000
Warfarin and salts.	1/1/1994
Zinc compounds: Includes any unique chemical substance that contains zinc as part of that chemical's infrastructure.	1/1/1987

* * * * *

[FR Doc. 2024–09428 Filed 5–1–24; 8:45 am]

BILLING CODE 6560–50–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 240429–0120]

RIN 0648–BM71

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Framework Adjustment 66

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This action approves and implements Framework Adjustment 66 to the Northeast Multispecies Fishery Management Plan (FMP). This rule sets catch limits for 8 of the 20 multispecies stocks, modifies the accountability measure (AM) implementation catch threshold for Atlantic halibut, and makes a temporary modification to the AM implementation catch threshold for the scallop fishery for Georges Bank (GB) yellowtail flounder. This action is necessary to respond to updated scientific information and to achieve the goals and objectives of the fishery management plan. The measures are intended to help prevent overfishing, rebuild overfished stocks, achieve optimum yield, and ensure that management measures are based on the best scientific information available.

DATES: Effective May 2, 2024.

ADDRESSES: Copies of Framework Adjustment 66, including the draft Environmental Assessment, the Regulatory Impact Review, and the Regulatory Flexibility Act Analysis prepared by the New England Fishery Management Council in support of this action, are available from Dr. Cate O'Keefe, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. The supporting documents are also accessible via the internet at: *http://www.nefmc.org/management-plans/northeast-multispecies* or *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Policy Analyst, phone: 978–282–8493; email: *Liz.Sullivan@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Summary of Approved Measures

The New England Fishery Management Council (Council) adopted Framework Adjustment 66 to the Northeast Multispecies FMP on December 7, 2023. The Council submitted Framework 66, including an environmental assessment (EA), for NMFS approval on February 16, 2024. NMFS published a proposed rule for Framework 66 on March 22, 2024 (89 FR 20412), with a 15-day comment period that closed on April 8, 2024.

Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and on behalf of the Secretary of Commerce, the Greater Atlantic Regional Fisheries Office's Regional Administrator (Regional Administrator) approves, disapproves, or partially approves measures that the Council proposes, based on consistency with the Magnuson-Stevens Act and other applicable law. NMFS reviews recommended specifications and proposed measures for consistency with the fishery management plan, plan amendments, the Magnuson-Stevens Act and other applicable law, and publishes proposed regulations, solicits public comment, and promulgates final regulations. Based on information provided in the EA and considered during the preparation of this action, and after consideration of comments, NMFS has approved all of the measures in Framework 66 recommended by the Council, as described below. The measures implemented in this final rule:

- Set shared U.S./Canada quotas for GB yellowtail flounder and eastern GB cod and haddock for fishing years 2024 and 2025;
- Set specifications, including catch limits for eight groundfish stocks: redfish, northern windowpane flounder, and southern windowpane flounder for fishing years 2024–2026; and GB cod, GB haddock, Gulf of Maine (GOM) haddock, GB yellowtail flounder, and white hake for fishing years 2024–2025;
- Make a minor adjustment to the subcomponent quotas for GOM cod and adjust the amount set aside for Canadian catch for Atlantic halibut;
- Remove the management uncertainty buffer for sectors for GOM haddock and white hake if the at-sea monitoring (ASM) target coverage level is set at 90 percent or greater for the 2024 and 2025 fishing years;
- Modify the catch threshold for implementing the Atlantic halibut accountability measures (AM); and
- Temporarily modify the catch threshold for implementing the scallop fishery's AM for GB yellowtail flounder.

This action also makes minor, clarifying regulatory changes that are not part of Framework 66, but are implemented under section 305(d) authority in the Magnuson-Stevens Act to make changes necessary to carry out the FMP. NMFS is making these changes in conjunction with the Framework 66 proposed measures for expediency purposes. These changes are described below under the heading, Minor, Clarifying Regulatory Changes under Secretarial Authority.

Fishing Years 2024 and 2025 Shared U.S./Canada Quotas

Management of Transboundary Georges Bank Stocks

As described in the proposed rule, eastern GB cod, eastern GB haddock, and GB yellowtail flounder are jointly managed with Canada under the United States/Canada Resource Sharing Understanding. This action adopts shared U.S./Canada quotas for these stocks for fishing year 2024 based on 2023 assessments and the recommendations of the Transboundary Management Guidance Committee (TMGC) and consistent with the Council's Scientific and Statistical Committee (SSC) recommendations. Framework 66 sets the same shared quotas for a second year (*i.e.,* for fishing year 2025) as placeholders, with the expectation that those quotas will be reviewed annually and new recommendations will be received from the TMGC. The 2024 and 2025 shared U.S./Canada quotas, and each country's allocation, are listed in table 1.

TABLE 1—2024 AND 2025 FISHING YEARS U.S./CANADA QUOTAS (metric tons (mt), live weight) AND PERCENT OF QUOTA ALLOCATED TO EACH COUNTRY

Quota	Eastern GB cod	Eastern GB haddock	GB yellowtail flounder
Total Shared Quota	520	10,000	168.
U.S. Quota	151 (29 percent)	3,100 (31 percent)	71 (42 percent).

TABLE 1—2024 AND 2025 FISHING YEARS U.S./CANADA QUOTAS (metric tons (mt), live weight) AND PERCENT OF QUOTA ALLOCATED TO EACH COUNTRY—Continued

Quota	Eastern GB cod	Eastern GB haddock	GB yellowtail flounder
Canadian Quota	369 (71 percent)	6,900 (69 percent)	97 (58 percent).

The regulations implementing the U.S./Canada Resource Sharing Understanding at 50 CFR 648.85(a) require deducting any overages of the U.S. quota for eastern GB cod, eastern GB haddock, or GB yellowtail flounder from the U.S. quota in the following fishing year. If catch information for the 2023 fishing year indicates that the U.S. fishery exceeded its quota for any of the shared stocks, NMFS will reduce the respective U.S. quotas for the 2024 fishing year in a future management action, as close to May 1, 2024, as possible. If any fishery that is allocated a portion of the U.S. quota exceeds its allocation and causes an overage of the overall U.S. quota, the overage reduction would be applied only to that fishery's allocation in the following fishing year. This ensures that catch by one component of the overall fishery does not negatively affect another component of the overall fishery.

Catch Limits for Fishing Years 2024–2026

Summary of the Catch Limits

This rule adopts catch limits for redfish, northern windowpane flounder, and southern windowpane flounder for the 2024–2026 fishing years, based on stock assessments completed in 2023, and catch limits for GB cod, GB haddock, GOM haddock, GB yellowtail flounder, and white hake for fishing years 2024–2025. Framework 65 (86 FR 40353, July 28, 2021) previously set 2024–2025 quotas for the remaining groundfish stocks, other than GOM cod, based on assessments conducted in 2022, and those remain in place. Framework 63 (87 FR 42375, July 15, 2022) previously set the 2024 quota for GOM cod, based on an assessment conducted in 2021, and that also remains in place. The catch limits implemented in this action, including overfishing limits (OFL), acceptable biological catches (ABC), and annual catch limits (ACL), are listed in tables 2 through 10. A summary of how these catch limits were developed, including the distribution to the various fishery components, was provided in the proposed rule and in appendix II (Calculation of Northeast Multispecies Annual Catch Limits, FY 2024–FY 2026) to the EA, and is not repeated here. The sector and common pool sub-ACLs implemented in this action are based on fishing year 2024 potential sector contributions (PSC) and preliminary fishing year 2024 sector rosters.

Management Uncertainty Buffer for Sectors

NMFS approves the measure in Framework 66 that removes the management uncertainty buffer for the sector sub-ACL for GOM haddock and white hake if the ASM coverage target is 90 percent or higher. This measure remains in place for the next 2 fishing years unless the Council adopts, and NMFS approves and implements, new specifications for fishing year 2025 based on updated assessments.

Amendment 23 (87 FR 75852, December 9, 2022) implemented a measure to remove the management uncertainty buffer for the sector sub-ACL for each allocated groundfish stock in years that the ASM coverage target is set at 100 percent, unless otherwise warranted. On February 20, 2024, the Regional Administrator announced the preliminary ASM coverage target of 100 percent and nothing has changed since that announcement to require a lower ASM coverage target. Therefore, in this action, NMFS is removing the management uncertainty buffer for each allocated stock for all sectors for the entirety of the 2024 fishing year. If the Regional Administrator makes a final determination with a lower ASM coverage target, the sectors' buffers will not be reinstated. Because the removal of the buffer is dependent on the annual determination of the ASM coverage target and consideration of its merit, the determination regarding the buffer in fishing year 2025 would be made in a future action.

TABLE 2—FISHING YEARS 2024–2026 OVERFISHING LIMITS AND ACCEPTABLE BIOLOGICAL CATCHES

[mt, live weight]

Stock	2024		Percent change from 2023	2025		2026	
	OFL	U.S. ABC		OFL	U.S. ABC	OFL	U.S. ABC
GB Cod	UNK	535	3	UNK	.....	.....	.....
GOM Cod	980	551	0	.....	.....	.....	.....
GB Haddock	17,768	7,058	−41	15,096	5,382	.....	.....
GOM Haddock	2,651	2,406	−4	2,549	2,312	.....	.....
GB Yellowtail Flounder	UNK	71	−33	UNK	71	.....	.....
SNE/MA Yellowtail Flounder	89	40	0	345	40	.....	.....
CC/GOM Yellowtail Flounder	1,279	992	−11	1,184	915	.....	.....
American Plaice	7,091	5,520	−3	6,763	5,270	.....	.....
Witch Flounder	UNK	1,256	0	UNK	1,256	.....	.....
GB Winter Flounder	2,153	1,549	−9	2,100	1,490	.....	.....
GOM Winter Flounder	1,072	804	0	1,072	804	.....	.....
SNE/MA Winter Flounder	1,425	627	0	1,536	627	.....	.....
Redfish	11,041	8,307	−17	10,982	8,273	11,177	8,418
White Hake	2,607	1,934	5	2,591	1,921	.....	.....
Pollock	18,208	13,940	−7	17,384	13,294	.....	.....
N Windowpane Flounder	UNK	136	−15	UNK	136	UNK	136
S Windowpane Flounder	284	213	−45	284	213	284	213
Ocean Pout	125	87	0	125	87	.....	.....
Atlantic Halibut	UNK	78	−9	UNK	78	.....	.....

TABLE 2—FISHING YEARS 2024–2026 OVERFISHING LIMITS AND ACCEPTABLE BIOLOGICAL CATCHES—Continued

[mt, live weight]

Stock	2024		Percent change from 2023	2025		2026	
	OFL	U.S. ABC		OFL	U.S. ABC	OFL	U.S. ABC
Atlantic Wolffish	124	93	0	124	93	.....	.....

UNK = Unknown; CC = Cape Cod; SNE/MA = Southern New England/Mid-Atlantic.
Note: An empty cell indicates no OFL/ABC is adopted for that year. These catch limits would be set in a future action.

TABLE 3—CATCH LIMITS FOR THE 2024 FISHING YEAR

[mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GB Cod	534	406	395	11	.....	.....	.....	.....	43	86
GOM Cod	536	488	286	10	192	.....	.....	.....	48	0
GB Haddock	7,040	6,909	6,756	153	.....	131	.....	.....	0	0
GOM Haddock	2,346	2,268	1,479	31	759	22	.....	.....	48	8.0
GB Yellowtail Flounder	70	58	55	3.3	.....	.....	11.0	1.3	0	0
SNE/MA Yellowtail Flounder	40	35	27	7.6	.....	.....	2.7	.....	0.2	2.0
CC/GOM Yellowtail Flounder	990	921	881	39	.....	.....	.....	.....	30	40
American Plaice	5,513	5,457	5,315	142	.....	.....	.....	.....	28	28
Witch Flounder	1,254	1,204	1,163	41	.....	.....	.....	.....	19	31
GB Winter Flounder	1,548	1,532	1,488	44	.....	.....	.....	.....	0	16
GOM Winter Flounder	800	635	556	79	.....	.....	.....	.....	153	12.1
SNE/MA Winter Flounder	624	461	408	53	.....	.....	.....	.....	19	144
Redfish	8,303	8,303	8,226	77	.....	.....	.....	.....	0	0
White Hake	1,933	1,923	1,905	18	.....	.....	.....	.....	0	10
Pollock	13,934	12,818	12,696	122	.....	.....	.....	.....	627	488
N Windowpane Flounder	127	94	na	94	.....	.....	27	.....	0.0	6.8
S Windowpane Flounder	205	30	na	30	.....	.....	71	.....	6.4	98
Ocean Pout	83	49	na	49	.....	.....	.....	.....	0	34
Atlantic Halibut	75	58	na	58	.....	.....	.....	.....	16	1.2
Atlantic Wolffish	87	87	na	87	.....	.....	.....	.....	0	0

na: not allocated to sectors.

TABLE 4—CATCH LIMITS FOR THE 2025 FISHING YEAR *

[mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GB Haddock	5,111	5,011	4,894	117	.....	100	.....	.....	0	0
GOM Haddock	2,183	2,108	1,350	29	729	22	.....	.....	46	8
GB Yellowtail Flounder	69	56	53	3.3	.....	.....	11	1.3	0	0
SNE/MA Yellowtail Flounder	38	33	26	7.6	.....	.....	2.7	.....	0.2	2.0
CC/GOM Yellowtail Flounder	873	808	772	36	.....	.....	.....	.....	28	37
American Plaice	5,009	4,956	4,821	136	.....	.....	.....	.....	26	26
Witch Flounder	1,196	1,146	1,105	41	.....	.....	.....	.....	19	31
GB Winter Flounder	1,446	1,431	1,389	42	.....	.....	.....	.....	0	15
GOM Winter Flounder	772	607	528	79	.....	.....	.....	.....	153	12.1
SNE/MA Winter Flounder	604	441	388	53	.....	.....	.....	.....	19	144
Redfish	7,859	7,859	7,783	77	.....	.....	.....	.....	0	0
White Hake	1,826	1,816	1,798	18	.....	.....	.....	.....	0	10
Pollock	12,683	11,619	11,503	117	.....	.....	.....	.....	598	465
N Windowpane Flounder	127	94	na	94	.....	.....	27	.....	0.0	6.8
S Windowpane Flounder	205	30	na	30	.....	.....	71	.....	6.4	98

TABLE 4—CATCH LIMITS FOR THE 2025 FISHING YEAR *—Continued

[mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
Ocean Pout	83	49	na	49					0	34
Atlantic Halibut	75	58	na	58					16	1.2
Atlantic Wolffish	87	87	na	87					0	0

na: not allocated to sectors.
* Northeast multispecies stocks not included in table 4 do not have catch limits approved or proposed for fishing year 2025.

TABLE 5—CATCH LIMITS FOR THE 2026 FISHING YEAR *

[mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
Redfish	7,997	7,997	7,919	78					0	0
N Windowpane Flounder	127	94	na	94			27		0.0	7
S Windowpane Flounder	205	30	na	30			71		6	98

na: not allocated to sectors.
* Northeast multispecies stocks not included in table 5 do not have catch limits approved or proposed for fishing year 2026.

TABLE 6—FISHING YEARS 2024–2026 COMMON POOL TRIMESTER TACS

[mt, live weight]

Stock	2024			2025			2026		
	Trimester 1	Trimester 2	Trimester 3	Trimester 1	Trimester 2	Trimester 3	Trimester 1	Trimester 2	Trimester 3
GB Cod	3.1	3.8	4.3						
GOM Cod	4.8	3.2	1.8						
GB Haddock	41.3	50.5	61.2	31.5	38.5	46.7			
GOM Haddock	8.2	7.9	14.3	7.9	7.6	13.8			
GB Yellowtail Flounder	0.6	1.0	1.7	0.6	1.0	1.7			
SNE/MA Yellowtail Flounder	1.6	2.1	3.9	1.6	2.1	3.9			
CC/GOM Yellowtail Flounder	22.5	10.2	6.7	20.7	9.4	6.2			
American Plaice	105.3	11.4	25.6	100.5	10.9	24.4			
Witch Flounder	22.3	8.1	10.2	22.3	8.1	10.2			
GB Winter Flounder	3.5	10.6	29.9	3.4	10.2	28.8			
GOM Winter Flounder	29.2	29.9	19.7	29.2	29.9	19.7			
Redfish	19.3	23.9	33.9	19.2	23.8	33.7	19.5	24.2	34.4
White Hake	6.8	5.6	5.6	6.8	5.5	5.5			
Pollock	34.2	42.8	45.2	32.6	40.8	43.1			

TABLE 7—COMMON POOL INCIDENTAL CATCH TACS FOR THE 2024–2026 FISHING YEARS

[mt, live weight]

Stock	Percentage of common pool sub-ACL	2024	2025	2026
GB Cod	1.68	0.19		
GOM Cod	1	0.10		
GB Yellowtail Flounder	2	0.07	0.07	
CC/GOM Yellowtail Flounder	1	0.39	0.36	
American Plaice	5	7.12	6.79	
Witch Flounder	5	2.03	2.03	
SNE/MA Winter Flounder	1	0.53	0.53	

TABLE 8—PERCENTAGE OF INCIDENTAL CATCH TACS DISTRIBUTED TO EACH SPECIAL MANAGEMENT PROGRAM

Stock	Regular B DAS program (percent)	Eastern U.S./CA haddock SAP (percent)
GB Cod	60	40
GOM Cod	100	n/a

TABLE 8—PERCENTAGE OF INCIDENTAL CATCH TACS DISTRIBUTED TO EACH SPECIAL MANAGEMENT PROGRAM—Continued

Stock	Regular B DAS program (percent)	Eastern U.S./CA haddock SAP (percent)
GB Yellowtail Flounder	50	50
CC/GOM Yellowtail Flounder	100	n/a
American Plaice	100	n/a
Witch Flounder	100	n/a
SNE/MA Winter Flounder	100	n/a

n/a: not applicable.

TABLE 9—FISHING YEARS 2024–2026 INCIDENTAL CATCH TACS FOR EACH SPECIAL MANAGEMENT PROGRAM

[mt, live weight]

Stock	Regular B DAS program			Eastern U.S./Canada haddock SAP		
	2024	2025	2026	2024	2025	2026
GB Cod	0.11	.....	.....	0.08	.....	.....
GOM Cod	0.10	.....	.....	n/a	n/a	n/a
GB Yellowtail Flounder	0.03	0.03	.....	0.03	0.03	.....
CC/GOM Yellowtail Flounder	0.39	0.36	.....	n/a	n/a	n/a
American Plaice	7.12	6.79	.....	n/a	n/a	n/a
Witch Flounder	2.03	2.03	.....	n/a	n/a	n/a
SNE/MA Winter Flounder	0.53	0.53	.....	n/a	n/a	n/a

n/a: not applicable.

TABLE 10—FISHING YEARS 2024–2026 REGULAR B DAS PROGRAM QUARTERLY INCIDENTAL CATCH TACS

[mt, live weight]

Stock	2024				2025				2026			
	1st Quarter (13%)	2nd Quarter (29%)	3rd Quarter (29%)	4th Quarter (29%)	1st Quarter (13%)	2nd Quarter (29%)	3rd Quarter (29%)	4th Quarter (29%)	1st Quarter (13%)	2nd Quarter (29%)	3rd Quarter (29%)	4th Quarter (29%)
GB Cod	0.01	0.03	0.03	0.03	.....	.....	.....	.....	.....	.....	.....	.....
GOM Cod	0.01	0.03	0.03	0.03	.....	.....	.....	.....	.....	.....	.....	.....
GB Yellowtail Flounder	0.00	0.01	0.01	0.01	0.00	0.01	0.01	0.01	.....	.....	.....	.....
CC/GOM Yellowtail Flounder	0.05	0.11	0.11	0.11	0.05	0.11	0.11	0.11	.....	.....	.....	.....
American Plaice	0.92	2.06	2.06	2.06	0.88	1.97	1.97	1.97	.....	.....	.....	.....
Witch Flounder	0.26	0.59	0.59	0.59	0.26	0.59	0.59	0.59	.....	.....	.....	.....
SNE/MA Winter Flounder	0.07	0.15	0.15	0.15	0.07	0.15	0.15	0.15	.....	.....	.....	.....

Sector Annual Catch Entitlements (ACE)

On April 5, 2024, NMFS allocated stocks to each sector, based on the fishing year 2024 catch limits set by prior frameworks (89 FR 23941, April 5, 2024). This rule updates the ACE allocated to sectors based on the catch limits approved in Framework 66, fishing year 2024 PSC, and preliminary fishing year 2024 sector rosters. NMFS calculates a sector's allocation for each stock by summing its members' PSC for the stock and then multiplying that total percentage by the commercial sub-ACL for that stock. The process for allocating ACE to sectors is further described in the rule allocating ACE to sectors for fishing year 2024 and is not repeated here (see 89 FR 23941, April 5, 2024).

Table 11 shows the cumulative PSC by stock for each sector for fishing year 2024. Tables 12 and 13 show the ACEs allocated to each sector for fishing year 2024, in pounds (lb) and mt, respectively. The common pool sub-ACLs are included in tables 11 through 13 for comparison. All permits enrolled in a sector, and the vessels associated with those permits, have until April 30, 2024, to withdraw from a sector and fish in the common pool for the 2024 fishing year. In addition, all permits that change ownership after the roster deadline of March 13, 2024, may join a sector through April 30, 2024. NMFS will publish final sector and common pool sub-ACLs based on final 2024 rosters as soon as practicable after the start of the 2024 fishing year.

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Table 11 -- Cumulative PSC (percentage) each sector is receiving by stock for fishing year 2024

Sector Name	MRI Count	GB Cod	GOM Cod	GB Haddock	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	59	10.66368130	0.69697957	1.73925106	0.19342970	1.33811259	0.20776918	1.80040167	0.69211258	1.41865619	2.25552402	2.03553546	0.96475271	0.55322185	0.98718417	2.69363866
Maine Coast Community Sector	106	2.14346576	15.77574417	3.28033123	12.14315523	1.94946572	2.52115190	6.24764686	15.57467423	12.30874340	0.80738762	7.86986961	2.23258492	9.19242287	13.81106273	12.67065727
Maine Permit Bank	11	0.13439158	1.16146439	0.04453277	1.12519137	0.01387770	0.03207071	0.31964833	1.16764302	0.72914170	0.00021875	0.42733162	0.01820600	0.82280520	1.65671908	1.69628627
Mooncusser Sector	48	12.02921920	6.25777157	3.84823447	3.69074677	1.23201147	0.86256446	3.02845586	0.86052723	1.81794552	0.95245393	2.85202511	2.48746222	4.75054253	10.67782404	10.53593863
NEFS 2	134	9.49872888	27.03357997	14.42403106	25.27417443	3.91163986	6.84782846	27.91222741	15.67097593	20.79218577	4.45167800	27.91508790	5.66793541	21.97944839	13.34211300	18.13675481
NEFS 4	58	8.63064256	11.18021805	6.05566788	8.86146971	2.17847227	2.28497979	6.42213790	9.43836833	8.82303299	0.69996269	7.42431329	1.03538340	6.69552217	8.27302876	7.26648727
NEFS 5	18	0.45848210	0.32875539	0.45599711	0.11135826	0.74730041	15.06499951	0.92544848	0.29012444	0.46535873	0.19884758	0.84381463	9.55163414	0.01340476	0.06758295	0.06684655
NEFS 6	3	0.53277963	0.16897341	0.55629310	0.15125674	0.06623359	0.00032970	0.02492228	0.88199052	0.47903664	0.08026315	0.07106409	0.01437459	1.11265001	0.52914348	0.31850611
NEFS 8	107	32.14429894	6.47349254	39.69437836	19.01532607	41.10369352	17.89837197	18.46919615	21.30707462	20.59414302	56.89277908	6.45104508	39.87083431	26.35138368	19.18519781	18.73824650
NEFS 10	23	0.36099982	1.80011246	0.11620637	1.06678057	0.00106541	0.56787338	3.22717458	0.44936350	0.95408609	0.01076846	7.06053027	0.54528800	0.01774808	0.05484715	0.08997485
NEFS 11	42	0.39886389	11.36750608	0.03379870	2.73739463	0.00147257	0.01232212	2.28957044	1.51568258	1.54445775	0.00310767	2.00546790	0.02573992	1.86957788	4.01717963	8.77006607
NEFS 12	25	0.66695944	3.70211898	0.15518034	1.33202724	0.00051982	0.03715834	9.30680020	1.54946832	1.79775784	0.00058497	12.24691996	0.33391380	0.54739034	0.89356742	1.39219765
NEFS 13	65	11.00132100	0.56476011	16.41446401	0.88555368	34.45892048	23.09421386	7.31716540	7.59921581	7.70632237	19.12551115	2.08860917	16.34008330	1.80768009	1.33448880	1.35854205
New Hampshire Permit Bank	4	0.00082696	1.15165725	0.00003421	0.03236683	0.00002041	0.00001803	0.02192453	0.02856511	0.00617882	0.00000326	0.06080509	0.00003694	0.01942367	0.08147906	0.11143280
Sustainable Harvest Sector 1	59	6.59488586	6.97935052	8.49027525	16.80493455	6.25856384	5.46705969	4.82490089	16.51623947	13.41249257	10.92899272	4.02657897	5.54519351	18.46133885	20.22470442	11.80101981
Sustainable Harvest Sector 2	20	1.75601730	1.68695288	2.35874044	4.19777672	0.93533973	1.71793597	2.56396440	2.81484093	2.78750859	0.63465289	3.06112792	2.50774026	4.79387649	3.44070357	3.23580284
Sustainable Harvest Sector 3	3	0.08038283	0.18792499	0.00389341	0.25359846	0.00000000	0.48368689	0.80290989	0.90262401	0.81756929	0.00000000	0.58666734	0.78545860	0.03544103	0.43984416	0.11493299
Common Pool	479	2.90405294	3.48263768	2.32869024	2.12345904	5.80329061	22.89966603	4.49550472	2.74050939	3.54538270	2.95726407	12.97320661	12.07337797	0.97612211	0.98332978	1.00266889
Sector Total	785	97.10	96.52	97.67	97.88	94.20	77.10	95.50	97.26	96.45	97.04	87.03	87.93	99.02	99.02	99.00

Table 12 -- ACE (in 1,000 lb), by stock, for each sector for fishing year 2024 #^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	35	60	5	119	146	6	2	0	37	83	38	76	29	10	101	42	762
Maine Coast Community Sector	7	12	103	224	276	404	2	2	127	1,876	327	27	111	23	1,683	586	3,582
Maine Permit Bank	0	1	8	3	4	37	0	0	7	141	19	0	6	0	151	70	480
Mooncusser Sector	40	68	41	263	324	123	2	1	62	104	48	32	40	25	870	453	2,979
NEFS 2	32	53	177	986	1,214	842	5	5	568	1,888	553	151	393	58	4,025	566	5,128
NEFS 4	29	49	73	414	510	295	3	2	131	1,137	235	24	105	11	1,226	351	2,055
NEFS 5	2	3	2	31	38	4	1	12	19	35	12	7	12	98	2	3	19
NEFS 6	2	3	1	38	47	5	0	0	1	106	13	3	1	0	204	22	90
NEFS 8	107	181	42	2,713	3,340	633	52	14	376	2,567	547	1,923	91	408	4,826	814	5,298
NEFS 10	1	2	12	8	10	36	0	0	66	54	25	0	99	6	3	2	25
NEFS 11	1	2	74	2	3	91	0	0	47	183	41	0	28	0	342	170	2,480
NEFS 12	2	4	24	11	13	44	0	0	189	187	48	0	173	3	100	38	394
NEFS 13	37	62	4	1,122	1,381	29	44	18	149	916	205	647	29	167	331	57	384
New Hampshire Permit Bank	0	0	8	0	0	1	0	0	0	3	0	0	1	0	4	3	32
Sustainable Harvest Sector 1	22	37	46	580	714	560	8	4	98	1,990	357	369	57	57	3,381	858	3,337
Sustainable Harvest Sector 2	6	10	11	161	198	140	1	1	52	339	74	21	43	26	878	146	915
Sustainable Harvest Sector 3	0	0	1	0	0	8	0	0	16	109	22	0	8	8	6	19	32
Common Pool	10	15	22	159	178	67	7	17	87	314	90	97	174	117	170	40	269
Sector Total	323	547	630	6,675	8,219	3,260	120	60	1,943	11,718	2,564	3,281	1,226	899	18,135	4,201	27,990

Numbers are rounded to the nearest thousand pounds. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds of pounds.

^ The data in the table represent the total allocations to each sector.

Table 13 -- ACE (in metric tons), by stock, for each sector for fishing year 2024 #^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	16	27	2	54	66	3	1	0	17	38	17	35	13	4	46	19	345
Maine Coast Community Sector	3	5	47	102	125	183	1	1	58	851	148	12	50	10	764	266	1,625
Maine Permit Bank	0	0	3	1	2	17	0	0	3	64	9	0	3	0	68	32	218
Mooncusser Sector	18	31	19	119	147	56	1	0	28	47	22	15	18	11.5	395	205	1,351
NEFS 2	14	24	80	447	551	382	2	2	258	856	251	68	178	26	1,826	257	2,326
NEFS 4	13	22	33	188	231	134	1	1	59	516	106	11	47	5	556	159	932
NEFS 5	1	1	1	14	17	2	0	5	9	16	6	3	5	44	1	1	9
NEFS 6	1	1	1	17	21	2	0	0	0	48	6	1	0	0	92	10	41
NEFS 8	49	82	19	1,231	1,515	287	24	6	170	1,164	248	872	41	185	2,189	369	2,403
NEFS 10	1	1	5	4	4	16	0	0	30	25	12	0	45	3	1	1	12
NEFS 11	1	1	34	1	1	41	0	0	21	83	19	0	13	0	155	77	1,125
NEFS 12	1	2	11	5	6	20	0	0	86	85	22	0	78	2	45	17	179
NEFS 13	17	28	2	509	627	13	20	8	68	415	93	293	13	76	150	26	174
New Hampshire Permit Bank	0	0	3	0	0	0	0	0	0	2	0	0	0	0	2	2	14
Sustainable Harvest Sector 1	10	17	21	263	324	254	4	2	45	903	162	168	26	26	1,534	389	1,513
Sustainable Harvest Sector 2	3	4	5	73	90	63	1	1	24	154	34	10	20	12	398	66	415
Sustainable Harvest Sector 3	0	0	1	0	0	4	0	0	7	49	10	0	4	4	3	8	15
Common Pool	4	7	10	72	81	30	3	8	39	142	41	44	79	53	77	18	122
Sector Total	147	248	286	3,028	3,728	1,479	55	27	881	5,315	1,163	1,488	556	408	8,226	1,905	12,696

Numbers are rounded to the nearest metric ton, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 metric tons, but that sector may be allocated a small amount of that stock in pounds.

^ The data in the table represent the total allocations to each sector.

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Modification to the Catch Thresholds for Implementing Accountability Measures

As more fully described in the proposed rule, Framework 66 modifies the catch threshold for implementing the Atlantic halibut AMs. In the situation where the Atlantic halibut ACL is exceeded by more than the management uncertainty buffer, NMFS would take into account the landings from the Canadian fishery for the last calendar year and determine whether, when combined with the landings by U.S. fisheries (Federal and state), the total ABC had been exceeded as well. Framework 66 does not make any changes to the AMs themselves, which are a combination of a zero-possession limit and gear-area restrictions.

Framework 66 modifies the catch threshold for implementing the scallop fishery's AMs for GB yellowtail flounder for the 2024 and 2025 fishing years, so that the AMs for GB yellowtail flounder would only be implemented if the scallop fishery catch exceeds its sub-ACL by any amount and the total ACL is also exceeded. Unless this modification is extended in a future action, the underlying policy for implementing the scallop fishery's AM for GB cod would be in effect for catches in fishing year 2026 and beyond. This temporary modification is more fully described in the proposed rule.

Minor, Clarifying Regulatory Changes Under Secretarial Authority

Framework 66 makes minor, clarifying changes in the regulations. Specifically, this action revises § 648.90(a)(5)(i)(F) to reorganize the section to improve clarity and readability regarding the Atlantic halibut AMs.

Comments and Responses on Measures Proposed in the Framework 66 Proposed Rule

We received two comment submissions covering numerous issues regarding the Framework 66 proposed rule from Northeast Seafood Coalition (NSC) and a member of the public.

Specifications

Comment 1: NSC wrote in support of setting the ABC for white hake at 75 percent of the fishing mortality associated with maximum sustainable yield (F_{MSY}) for two years, citing that this will still allow for the stock to rebuild by 2031. NSC also supports increasing the GOM haddock ABC to the level of 90 percent F_{MSY} for fishing years 2024 and 2026, given the healthy population level and the potential economic impacts of a lower quota. A member of the public wrote in support of all the catch limits proposed in Framework 66.

Response 1: NMFS agrees and is approving the specifications as proposed.

Comment 2: NSC expressed concern regarding the proposed shared U.S./Canada quota for GB yellowtail flounder. NSC commented that the calculation of this quota follows a harvest strategy known as the Limiter Approach, designed to use data from three surveys. NSC noted that, in recent years, there have been missing survey data. NSC claims that the use of the Limiter Approach with missing survey data has not been adequately addressed. NSC recommends that NMFS prioritize scientific and management approaches that do not economically impact the commercial fishery, but does not provide an alternative to the quota that was recommended by the Council's SSC and by the TMGC, and proposed in Framework 66.

Response 2: NSC is echoing the concerns that the SSC raised when it made its recommendation of the shared U.S./Canada quota for GB yellowtail flounder of 168 mt. In the SSC's September 15, 2023, report to the Council, the SSC noted that it had previously accepted the use of the Limiter Approach despite the recognized uncertainty from having only two of the three surveys. In the last three years in which the Limiter Approach was used without all three surveys, sensitivity analyses were conducted to determine the potential impact of the missing information. For 2023, no adjustment was made to the Limiter Approach to account for the missing survey because these analyses showed that the impact of missing that particular survey was minimal.

The SSC also noted that the Yellowtail Flounder Research Track Stock Assessment was ongoing and evaluating alternative assessment approaches for GB yellowtail flounder to replace, or improve upon, the Limiter Approach. While the SSC acknowledged in its September 2023 report that fishing does not appear to be a ''major driver'' of stock status currently, it also argued that for a stock that has experienced overfishing historically and the causal mechanisms for lack of rebuilding are ''difficult to know with certainty,'' and therefore, the SSC advised caution when managing this stock. NMFS will continue to support the yellowtail research track assessment process (Memorandum from SSC to Dr. Cate O'Keefe, Council Executive Director, September 15, 2023).

Comment 3: NSC wrote in support of removing the management uncertain buffer for sectors for GOM haddock and white hake for the upcoming fishing year.

Response 3: NMFS agrees and is approving this measure. Additionally, because the management uncertainty buffer by regulation defaults to zero when the ASM coverage target is 100 percent, NMFS is removing the management uncertainty buffer for each allocated stock for all sectors for the entirety of the 2024 fishing year based on the preliminary ASM coverage target of 100 percent.

Accountability Measure Modifications

Comment 4: NSC supports the modifications of catch threshold for implementing AMs, for both Atlantic halibut and the scallop fishery's catch of GB yellowtail flounder.

Response 4: NMFS agrees and is approving both measures.

Changes From the Proposed Rule

NMFS made one change to the proposed rule. The proposed rule's section *Annual Catch Limits* included sector and common pool sub-ACLs based on fishing year 2023 PSCs and final fishing year 2023 sector rosters but did not include the PSCs and ACEs allocated to each sector. This final rule updates the total ACLs and sector and common pool sub-ACLs based on the ASM coverage target of 100 percent and the 2024 PSCs and preliminary fishing year 2024 sector rosters, and includes the PSCs and ACEs at the sector level.

Classification

NMFS is issuing this rule pursuant to sections 304(b)(3) and 305(d) of the Magnuson-Stevens Act, which provide specific authority for implementing this action. Pursuant to section 305(d), this action sets specifications for stocks managed by the Northeast Multispecies FMP as recommended by the Council, in accordance with § 648.90(a)(4), makes minor, clarifying changes in the regulations for the Northeast Multispecies FMP, and is necessary to carry out the Northeast Multispecies FMP. The NMFS Assistant Administrator has determined that this final rule is consistent with Framework Adjustment 66, the Northeast Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866, as amended by E.O. 14094. This final rule

does not contain policies with federalism or takings implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

The Assistant Administrator for Fisheries finds that waiver of the 30-day delayed effectiveness of this action pursuant to 5 U.S.C. 553(d)(1) and 553(d)(3) is justified. This action relies on the best available science to set fishing year 2024 catch limits for groundfish stocks and adopts several other measures to improve the management of the groundfish fishery. This final rule must be implemented as soon as possible to capture fully the conservation and economic benefits of Framework 66 and avoid adverse economic impacts.

This action was developed by the New England Fishery Management Council as part of the annual Framework Adjustment process, during which final action was taken in December 2023. The Council submitted the final Framework on February 16, 2024. Given the timing of the Council process and submission, the earliest NMFS was able to publish a proposed rule for Framework 66 was on March 22, 2024.

A delay in implementation of this rule increases negative economic effects for regulated entities. Several stocks did not have 2024 quotas set by a previous framework. A separate action implemented default quotas for those stocks (75 percent of the 2023 quota). For several stocks, the fishery is operating under lower quotas than those implemented by this rule. A delay could limit economic opportunities for the fishery, as well as lead to confusion and uncertainty. A delay would also increase the administrative burden and costs for groundfish sectors of tracking temporary quotas and coordinating fishing effort relating to those quotas, and then having to reprogram their data systems to adjust to the revised quotas. Providing timely access to these stocks is also a potential safety issue. A significant portion of fishing activity occurs in early summer, due to better weather, and, for some smaller vessels, summer may be the only season in which they are able to participate in the fishery.

Additionally, this rule contains no new measures (*e.g.,* gear requirements) for which regulated entities need time to prepare or revise their current practices. Fishermen who are subject to this action expect and need timely implementation to avoid adverse economic impacts. This action is similar to the process used to set quotas every 1–2 years, approves all items as proposed, and contains only quotas and minor adjustments to the management plan that were discussed at multiple noticed meetings where the public was provided opportunity to learn about the action, ask questions, and provide input into the development of the measures. Affected parties and other interested parties participated in this public process to develop this action and desire implementation as close to the beginning of the fishing year on May 1 as possible.

Section 553(d)(1) of the Administrative Procedure Act permits that the 30-day delay in effectiveness be waived for substantive rules that relieve a restriction (5 U.S.C. 553(d)(1)). Once this rule goes into effect, all fisherman impacted by the action will be under new quota limits that increase their opportunity to fish. Until the rule is in effect, those fishermen are effectively restricted in their opportunity to fish. Therefore, waiving the 30-day delay for this rule would relieve the restriction on the fishermen. Additionally, relieving the restriction on catch from application of the management uncertainty buffer increases available quota and provides economic opportunities, operational flexibility, and prevents potential earlier closures of fisheries.

In sum, a delay in implementation of this action would greatly diminish the benefits of these specifications and other approved measures. For these reasons, a 30-day delay in the effectiveness of this rule is impracticable and contrary to the public interest.

Final Regulatory Flexibility Analysis

Section 604 of the Regulatory Flexibility Act (RFA) requires Federal agencies to prepare a Final Regulatory Flexibility Analysis (FRFA) for each final rule that describes the economic impact of this action on small entities (5 U.S.C. 604). The FRFA includes a summary of significant issues raised by public comments, the analyses contained in Framework 66 and its accompanying Environmental Assessment, Regulatory Impact Review, and Initial Regulatory Flexibility Analysis (IRFA), the IRFA summary in the proposed rule, as well as the summary provided below. A statement of the necessity for and for the objectives of this action are contained in Framework 66 and in the preamble to this final rule, and is not repeated here.

A Summary of the Significant Issues Raised by the Public in Response to the IRFA, a Summary of the Agency's Assessment of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

NMFS received one comment expressing concern about the economic impacts of this action and has summarized the comments in the comments and responses section of this rule. None of the comments received were directly related to the IRFA, or provided information that changed the conclusions of the IRFA. The Chief Counsel for the Office of Advocacy of the Small Business Administration (SBA) did not file any comments. NMFS made no changes to the proposed rule measures.

Description and Estimate of the Number of Small Entities to Which the Rule Would Apply

The final rule impacts the recreational groundfish, Atlantic sea scallop, small mesh multispecies, Atlantic herring, and large-mesh non-groundfish fisheries. Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different FMPs, even beyond those impacted by the action. Furthermore, multiple-permitted vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of the RFA analysis, the ownership entities, not the individual vessels, are considered to be the regulated entities.

As of June 1, 2023, NMFS had issued 675 commercial limited-access groundfish permits associated with vessels (including those in confirmation of permit history (CPH)), 639 party/charter groundfish permits, 696 limited access and general category Atlantic sea scallop permits, 694 small-mesh multispecies permits, 73 Atlantic herring permits, and 752 large-mesh non-groundfish permits (limited access summer flounder and scup permits). Therefore, this action potentially regulates 3,529 permits. When accounting for overlaps between fisheries, this number falls to 2,029 permitted vessels. Each vessel may be individually owned or part of a larger corporate ownership structure and, for RFA purposes, it is the ownership entity that is ultimately regulated by the action. Ownership entities are identified on June 1st of each year based on the list of all permit numbers, for the most recent complete calendar year, that have

applied for any type of Greater Atlantic Region Federal fishing permit. The current ownership data set is based on calendar year 2022 permits and contains gross sales associated with those permits for calendar years 2018 through 2022.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System (NAICS) code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates) and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. The determination as to whether the entity is large or small is based on the average annual revenue for 2018 through 2022. The SBA has established size standards for all other major industry sectors in the U.S., including for-hire fishing (NAICS code 487210). These entities are classified as small businesses if combined annual receipts are not in excess of $8.0 million for all of an entity's affiliated operations. As with commercial fishing businesses, the annual average of the most recent years (2018–2022) is utilized in determining annual receipts for businesses primarily engaged in for-hire fishing.

Based on the ownership data, 1,538 distinct business entities hold at least one permit that this action regulates. All 1,538 business entities identified could be directly regulated by this action. Of these 1,538 entities, 871 are commercial fishing entities, 291 are for-hire entities, and 376 did not have revenues (*i.e.,* were inactive in 2022). Of the 871 commercial fishing entities, 860 are categorized as small entities and 11 are categorized as large entities, per the NMFS guidelines. Furthermore, 520 of these commercial fishing entities held limited access groundfish permits, with 516 of these entities being classified as small businesses and 4 of these entities being classified as large businesses. All 291 for-hire entities are categorized as small businesses.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Final Rule

The action does not contain any new collection-of-information requirements under the Paperwork Reduction Act.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes

The economic impacts of each measure are discussed in more detail in sections 6.5 and 7.12 of the Framework 66 Environmental Assessment (see **ADDRESSES**) and are not repeated here. NMFS notes that, overall, for the updated groundfish specifications and the modifications to the AMs in this final rule, the No Action alternative was the only other alternative considered by the Council. There are no significant alternatives that would minimize the economic impacts. The action is predicted to generate $40.8 million in gross revenues for the sector portion of the commercial groundfish trips. This amount is $20.4 million more than the amount of gross revenues under the No Action alternative, but $3.9 million less than the amount of gross revenues generated in fishing year 2022. Small entities engaged in common pool groundfish fishing are expected to be positively impacted by the action as well, relative to the No Action alternative. Small entities engaged in the recreational groundfish fishery are likely to be negatively impacted by the decrease in the GOM haddock sub-ACL. Sub-ACL decreases for groundfish stocks allocated to the Atlantic sea scallop fishery and the large-mesh non-groundfish fishery may negatively affect small entities engaged in those fisheries. The temporary modification to the scallop fishery's AM implementation catch threshold for GB yellowtail flounder for fishing years 2024 and 2025 will reduce the likelihood of negative impacts to the scallop fishery.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency will publish one or more guides to assist small entities in complying with the rule and will designate such publications as ''small entity compliance guides'' that will explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a bulletin to permit holders that also serves as a small entity compliance guide was prepared. This final rule and the guide (*i.e.,* bulletin) will be sent via email to the Greater Atlantic Regional Fisheries Office Northeast multispecies fishery email list, as well as the email lists for the scallop and herring fisheries, which receive an allocation of some groundfish stocks. The final rule and the guide are available from NMFS at: *https://www.fisheries.noaa.gov/management-plan/northeast-multispecies-management-plan.* Hard copies of the guide and this final rule will be available upon request (see **ADDRESSES**).

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: April 29, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, NMFS amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.90, revise paragraph (a)(5)(i)(F) and add paragraph (a)(5)(iv)(B) to read as follows:

§ 648.90 NE multispecies assessment, framework procedures and specifications, and flexible area action system.

* * * * *

(a) * * *

(5) * * *

(i) * * *

(F) *Atlantic halibut.* If NMFS determines, as described in paragraph (a)(5)(i)(D) of this section, that the overall ACL for Atlantic halibut is exceeded by catch from U.S. Federal and state fisheries by any amount greater than the management uncertainty buffer and, after accounting for the amount of landings of Atlantic halibut from Canadian fisheries, as appropriate, that the total ABC for Atlantic halibut has also been exceeded, the applicable AM shall be implemented as described in paragraph (a)(5)(i)(F)(*1*) of this section. If a sub-ACL for Atlantic halibut is allocated to another fishery, consistent with the process specified at § 648.90(a)(4), and there are AMs for that fishery, the multispecies fishery AM shall only be implemented if the sub-ACL allocated to the multispecies fishery is exceeded (*i.e.,* the sector and common pool catch for a particular stock, including the common pool's share of any overage of the overall ACL caused by excessive catch by other sub-components of the fishery pursuant to § 648.90(a)(5),

exceeds the common pool sub-ACL) and the overall ACL is also exceeded.

(*1*) *Description of AM.* When the AM is implemented, any vessel issued a Federal permit for any fishery management plan may not fish for, possess, or land Atlantic halibut for the fishing year in which the AM is implemented, as specified in paragraph (a)(5)(i)(F) of this section, unless otherwise specified in paragraph (a)(5)(i)(F)(*2*) of this section. Additionally, the applicable AM areas, as defined in paragraph (a)(5)(i)(F)(*4*) of this section, shall be implemented as follows: Any vessel issued a limited access NE multispecies permit and fishing with trawl gear in the Atlantic Halibut Trawl Gear AM Area may only use a haddock separator trawl, as specified in § 648.85(a)(3)(iii)(A); a Ruhle trawl, as specified in § 648.85(b)(6)(iv)(J)(*3*); a rope separator trawl, as specified in § 648.84(e); or any other gear approved consistent with the process defined in § 648.85(b)(6), except that selective trawl gear is not required in the portion of the Trawl Gear AM Area between 41 degrees 40 minutes and 42 degrees from April 1 through July 31. When in effect, a limited access NE multispecies permitted vessel with gillnet gear may not fish or be in the Atlantic Halibut Fixed Gear AM Area from March 1 through October 31, unless transiting with its gear stowed and not available for immediate use as defined in § 648.2, or such gear was approved consistent with the process defined in § 648.85(b)(6).

(*2*) *Vessels exempt from the no possession AM.* Vessels issued only a charter/party permit, and/or an Atlantic highly migratory species angling permit, and/or an Atlantic highly migratory species charter/headboat permit are exempt from the no possession AM. This exemption does not apply to any vessel that is issued any other permit that is subject to the AM. For example, a vessel issued a Northeast multispecies charter/party permit and a bluefish charter/party permit would be exempt from the no possession AM, but a vessel issued a Northeast multispecies charter/party permit and a commercial bluefish permit would not be exempt from the no possession AM.

(*3*) *Review of the AM.* If the overall ACL is exceeded by more than 20 percent, the Council shall revisit the AM in a future action.

(*4*) *Atlantic halibut AM area.* The AM areas defined below are bounded by the following coordinates, connected in the order listed by rhumb lines, unless otherwise noted.

TABLE 1 TO PARAGRAPH (a)(5)(i)(F)(*4*)

Atlantic halibut trawl gear AM area		
Points	N latitude	W longitude
1	42°00′	69°20′
2	42°00′	68°20′
3	41°30′	68°20′
4	41°30′	69°20′

TABLE 2 TO PARAGRAPH (a)(5)(i)(F)(*4*)

Atlantic halibut gillnet gear AM area		
Points	N latitude	W longitude
1	43°10′	69°40′
2	43°10′	69°30′
3	43°00′	69°30′
4	43°00′	69°40′

* * * * *

(iv) * * *

(B) *2024 and 2025 fishing year threshold for implementing the Atlantic sea scallop fishery AM for GB yellowtail flounder.* For the 2024 and 2025 fishing years, if scallop fishery catch exceeds the GB yellowtail flounder sub-ACL specified in paragraph (a)(4) of this section, and total catch exceeds the overall ACL for that stock, then the applicable scallop fishery AM will take effect, as specified in § 648.64 of the Atlantic sea scallop regulations. For the 2026 fishing year and onward, the threshold for implementing scallop fishery AMs for GB yellowtail flounder will return to that listed in paragraph (a)(5)(iv)(A) of this section.

* * * * *

[FR Doc. 2024–09569 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 86
Thursday, May 2, 2024

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0249]

RIN 1625–AA00

Safety Zone; Upper Mississippi River Mile 202.5–203.5 Near Alton, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for Upper Mississippi River at mile marker 202.5 to 203.2. This action is necessary to provide for the safety of life on these navigable waters near Alton, IL, during a power boat championship race on June 21, 2024, through June 24, 2024. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 14, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0249 using the Federal Decision-Making Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments. This notice of proposed rulemaking with its plain-language, 100-word-or-less proposed rule summary will be available in this same docket.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email MST1 Benjamin Conger, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2573, email *Benjamin.D.Conger@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

Great Rivers and Routes Tourism Bureau in Alton, IL, notified the Coast Guard that it will be conducting a power boat championship race from 6 a.m. to 8 p.m. on June 21 to June 24, 2024. The power boat championship race will be held on the Upper Mississippi River, near the Alton riverfront between the Clark Bridge and Argosy Casino. Hazards from the high-speed power boat racers include accidental collisions and serious or significant harm to others. The Captain of the Port Sector Upper Mississippi River (COTP) has determined that potential hazards associated with the high-speed power boats would be a safety concern for anyone within the Upper Mississippi River from mile marker 202.5 to 203.2. Race and event officials have scheduled multiple openings to allow for vessels to transit.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within the Upper Mississippi River from mile marker 202.5 to 203.2, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a safety zone from 6 a.m. to 8 p.m. on June 21 through June 24, 2024. The safety zone would cover all navigable waters of the Upper Mississippi River from mile marker 202.5–203.5 near Alton, IL. The duration of the zone is intended to ensure the safety of vessels and these navigable waters during the scheduled 6 a.m. to 8 p.m. power boat championship race, with scheduled openings throughout the 3 day period. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on a safety zone located on the Upper Mississippi River mile markers 202.5–203.2 near Alton, IL. The safety zone will be active only while the power boat championship race is being conducted, from June 21, 2024, until June 24, 2024.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see

ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting from 6 a.m. to 8 p.m. that would prohibit entry of Upper Mississippi River from mile marker 202.5 to 203.2. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision-Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG–2024–0249 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you click on the Dockets tab and then the proposed rule, you should see a ''Subscribe'' option for email alerts. The option will notify you when comments are posted, or a final rule is published.

We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0706 to read as follows:

§ 165.T08–0706 Safety Zone; Upper Mississippi River, Mile Markers 202.5–203.2, Alton, IL.

(a) Location. The following area is a safety zone: all navigable waters within the Upper Mississippi River, Mile Markers (MM) 202.5–203.2.

(b) Enforcement period. This section is subject to enforcement from June 21, 2024 through June 24, 2024.

(c) Regulations. (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) Informational broadcasts. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone as ice or flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: April 22, 2024.

A.R. Bender,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2024–09001 Filed 5–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 240415–0108]

RIN 0648–BK65

Proposed Rule To Modify the Duration of Certain Permits and Letters of Confirmation Under the Marine Mammal Protection Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to modify the regulations for Marine Mammal Protection Act (MMPA) section 104 permits, including scientific research, enhancement, photography, and public display permits and Letters of Confirmation (LOCs). The modification would remove the 5-year regulatory limitation on the duration of section 104 permits and LOCs. This would give NMFS the discretion to issue these permits for longer than 5 years where such a duration would be appropriate. This proposed rule would apply only to permits and authorizations issued under section 104 of the MMPA.

DATES: Comments and information must be received no later than June 3, 2024.

ADDRESSES: A plain language summary of this proposed rule is available at *https://www.regulations.gov/docket/NOAA-NMFS-2024-0054.* You may submit comments on this document, identified by NOAA–NMFS–2024–0054, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2024–0054 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; ATTN: Jolie Harrison, Chief, Permits and Conservation Division.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Sara Young or Carrie Hubard, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Authority for Action

Under section 104 of the MMPA (16 U.S.C. 1374), NMFS may issue permits for the take or importation of marine mammals for:

- scientific research (MMPA section 104 (c)(3));
- enhancing the survival or recovery of the species or stock (MMPA section 104 (c)(4));
- public display (MMPA section 104 (c)(2));
- commercial or educational photography (MMPA section 104(c)(6)); and
- scientific research that may result only in taking by Level B harassment under the MMPA's General Authorization provisions (MMPA section 104 (c)(3)). Level B harassment refers to activities that have the potential to disturb but not injure a marine mammal.

The implementing regulations for scientific research, enhancement, public display, and photography permits can be found at 50 CFR 216.31–216.41. The implementing regulations for issuing LOCs under the General Authorization can be found at § 216.45. Applying for an LOC is a simpler and more expedited process than applying for a scientific research permit. An LOC confirms that an applicant's proposed research activities will only result in Level B harassment (*i.e.,* activities with the potential to disturb but not injure) and will only target marine mammals that are not endangered or threatened under the Endangered Species Act (ESA). A scientific research permit is required for research on ESA-listed species or for research that involves physical contact with marine mammals.

Background

Section 2 of the MMPA, 16 U.S.C. 1361, provides that it is the Sense of Congress that marine mammals ''should be protected and encouraged to develop to the greatest extent feasible commensurate with sound policies of resource management and that the primary objective of their management should be to maintaining the health and stability of the marine ecosystem.'' Section 2, however, also includes Congress's finding that there is inadequate knowledge of the ecology and population dynamics of marine mammals. Since the MMPA was enacted in 1972, NMFS has issued permits to allow research on marine mammals as well as other permits and authorizations allowing take of marine mammals as specified in section 104.

Take, as defined in section 3 of the MMPA, 16 U.S.C. 1362, and in § 216.3,

means to harass, hunt, capture, collect, kill marine mammals, or any attempt to do so. While the permit types that are the subject of this rule authorize take of marine mammals, the majority of the take authorized under these permits is for harassment of marine mammals or collection of samples rather than lethal take. For example, a typical photography permit authorizes filming of marine mammals by underwater divers or via a drone to collect footage for a documentary series. Most LOCs under the GA are issued to researchers who photograph bottlenose dolphins (*Tursiops truncatus*) to identify individuals and study distribution and social patterns. Some research permits authorize scientists to import marine mammal biological samples to study disease, genetics, prey species, and hormones. Research permits cover a wide variety of projects, such as capturing, sampling, tagging, and releasing seals to find out how deep they dive or remotely biopsy sampling and tagging large whales to study their migrations.

Section 104 permits like those described above authorize activities that promote the goals set out in section 2 of the MMPA. Most permits authorize research on marine mammals, which ultimately benefits the species. As scientists conduct permitted research, they expand our knowledge of the abundance, distribution, and health of these animals. Resource managers then use that best available data to inform their decisions. NMFS also issues permits for commercial and educational photography of non-endangered marine mammals. The final product of these permits might, for example, be a documentary television series that may inspire awe, share conservation messages, and educate the public about marine mammals.

Section 104(b) of the MMPA requires that all permits specify ''the period during which the permit is valid.'' The MMPA does not limit how long section 104 permits or LOCs can be valid. However, there are regulatory limitations that prevent MMPA section 104 permits and LOCs from being valid longer than 5 years (§§ 216.35 and 216.45, respectively). This proposed rule would remove the 5-year regulatory limitation on the duration of MMPA section 104 permits and LOCs. This would allow NMFS to issue section 104 permits and LOCs for longer than 5 years, as appropriate. Each permit would have an expiration date, tailored to the specific activities proposed by the applicant, which would be subject to public comment.

Need for the Action

NMFS has been issuing marine mammal permits under section 104 for almost 50 years, and NMFS' implementing regulations have not been updated since 1996. Based on decades of experience with the issuance of these permits and the activities conducted pursuant to them, we believe a change is warranted to allow section 104 permits with durations greater than 5 years, in certain circumstances, as discussed below.

Most MMPA section 104 permits (93 percent of current permits) are scientific research permits, which result in data that informs management and conservation of marine mammal species. Rigorous studies of these long-lived species often require years, even decades, of data collection. Sixty percent of the current scientific research permit holders have had a permit for 20 or more years, meaning four or more permit cycles. Seventeen permit holders have held a permit for more than 40 years. Many researchers have dedicated their careers to conducting longitudinal studies. For example, one research group has been studying the population dynamics of Weddell seals (*Leptonychotes weddellii*) since 1968, while another scientist has been studying dolphins in Florida for over 50 years. NMFS science centers have held MMPA research permits since the creation of the MMPA and continue to hold 13 permits today. The MMPA requires NMFS to compile abundance and distribution data on marine mammals and publish the findings as Stock Assessment Reports. The need for these research activities is expected to continue into the extended future and is an example of why a permit of longer than 5 years in duration may be appropriate. Regardless of the requested duration of research, every application for a permit or authorization would include justification for the requested duration and all permits and authorizations issued would have expiration dates.

Another potential example of a permit that may merit a longer time period might be for non-releasable marine mammals maintained in permanent care in academic facilities, zoos, and aquariums for research or enhancement purposes for the duration of their lives. Under the proposed change, these permit holders might request a permit for longer than 5 years, and the agency may, in certain circumstances, depending on the specifics of the research or enhancement, issue a permit for a longer term.

Because NMFS has been issuing permits for decades, the effects of specific permitted activities on marine mammals, including particular research techniques, are well known. Most research methodologies have become standardized over time. Permit holders tend to request and use the same techniques year after year because they are effective and create continuity across their long-term data sets. As a result, the impacts of their activities conducted under consecutive permits is expected to be the same or similar. Historically, moreover, research and filming methods, have not raised significant public concern. As required by statute, NMFS gives the public the opportunity to comment on permit applications it processes, via notice in the **Federal Register**. Substantive comments have been received infrequently over the course of the permit program. Proposed activities are evaluated to ensure they are humane as required by issuance criteria (see *Implementation and Oversight* section). Researchers working under a scientific research permit studying marine mammal parts typically conduct analyses in a laboratory using marine mammal samples without interacting with wild animals. Researchers working under an LOC and filmmakers working under a commercial photography permit are restricted to activities that only have the potential to disturb (not kill or physically injure) marine mammals. They are not allowed to conduct any activity that has the potential to injure an animal, including any physical contact. Additionally, most filmmakers and many researchers want to observe and record natural marine mammal behavior. As a result, they can be expected to conduct their activities in a manner that avoids or minimizes any reaction of the animals to the permitted activity.

An additional benefit of removing the 5-year restriction on permits would be to make the MMPA permitting regulations consistent with those of the ESA. Many permits are issued under both the MMPA and ESA because the target species are marine mammals that are listed as threatened or endangered, and thus protected under both statutes. Unlike the current MMPA regulations, the ESA section 10 permit regulations do not limit the number of years an ESA section 10(a)(1)(A) scientific research and enhancement permit may be valid (50 CFR part 222) Consistency between the MMPA and ESA permitting regulations with respect to permit duration would allow NMFS to issue joint MMPA–ESA permits with terms of

longer than 5 years, if warranted. NMFS currently issues some 10-year ESA permits for scientific research and enhancement on species such as sawfish, sea turtles, and sturgeon. NMFS cannot currently do the same for permits involving marine mammals because of the 5-year limit on permit duration under the MMPA regulations, even if the research would otherwise qualify for a 10-year permit under the ESA.

This change would provide greater flexibility and efficiency to permit applicants and the agency. Increasing the permit durations would decrease how often researchers have to apply for a permit, thus decreasing the amount of time and effort required in reapplying to continue their research. As shown above, decades of permit data show that researchers tend to apply for multiple permits throughout their career. Lengthening permit duration where appropriate would promote efficiency and lessen the burden on our permit holders, while still providing the same protections for marine mammals as mandated by the MMPA.

Implementation and Oversight

Information Required in Applications

Applications for MMPA section 104 special exception permits and LOCs would be evaluated and processed in the same manner as they are now in accordance with 50 CFR part 216. Applicants would still have to include their proposed start and end dates, as well as a description of the frequency and seasonality of their proposed activities in their application. Currently, applicants for section 104 permits and LOCs can request a time period of 5 years or less. Under the proposed change, applicants may request a permit duration longer than 5 years, which may be more appropriately aligned with the project's goals rather than an arbitrary 5 year duration. The agency may, in its discretion, issue a permit for such a term, provided the proposed duration is justified and appropriate for the applicant's project and objectives, is supported by the applicant's history with previous MMPA permits, has undergone public comment, and meets all statutory and regulatory issuance criteria. All permits and authorizations issued would have expiration dates. While NMFS proposes to remove the 5-year regulatory maximum duration, NMFS expects that there will continue to be projects for which a permit for a terms of 5 years or less will be appropriate. For example, permits such as those for commercial or educational photography are issued for discrete projects that take place at specific times, rarely requiring more than a year or two. Similarly, permits for importation of marine mammals for public display are issued for a singular or discrete action, which would typically warrant a permit of short duration. Thus, the duration of the permit would be determined based on the specific project proposed and the justified duration of that project.

Opportunity for Public Comment

This proposed regulatory change would not remove the public's opportunity to comment on permit applications and any major permit amendments. NMFS would continue to publish notices in the **Federal Register** for a 30-day public comment period when complete permit applications and requests for major amendments are received consistent with statutory and regulatory requirements (16 U.S.C. 1374(d) and § 216.33(d), respectively). These notices provide the public an opportunity to comment on the proposed permit duration. NMFS would also continue to solicit comments from the Marine Mammal Commission consistent with § 216.33(d)(2), and other relevant federal and state agencies in accordance with § 216.33(d)(3), concurrent with the public comment period. NMFS would continue to consider all public and expert comments on a proposed permit application, including the proposed duration, prior to permit issuance. Substantial public interest in a particular application might warrant a term of 5 years or less, to provide the public with more frequent opportunities to comment. LOCs do not currently require a public comment period and that would not change.

Issuance Criteria

To obtain an MMPA section 104 permit, applicants must meet certain statutory and regulatory issuance criteria. This includes, among other things, the regulatory issuance criteria at § 216.34, which require applicants to demonstrate, for the time period proposed, that the activity is:

- humane and with no unnecessary risks;
- consistent with regulatory restrictions;
- consistent with the purposes and policies of the ESA (if threatened or endangered species are involved);
- not likely to have a significant adverse impact on the species or stock;
- conducted by personnel with expertise and adequate facilities and resources;
- conducted by personnel with adequate resources for marine mammals held captive or transported; and
- that any requested import or export will not likely result in additional taking.

Additional criteria apply for depleted, threatened, and endangered marine mammals. These criteria would still apply regardless of permit duration.

In addition to the regulatory criteria above, NMFS would also consider whether the applicant has previously held a permit, and if so, whether they have successfully carried out the permitted objectives. For example, for research permits, this may include whether the permit holder obtained funding, collected data, and made the results available to the scientific community in a reasonable period. As explained above (see *Need for Action*), most permits issued under section 104 have not raised substantial public concern, and the impacts of many activities conducted under section 104 permits are well known. If an applicant proposes activities that are considered novel or are likely to be controversial, a shorter permit duration may be warranted.

Agency Oversight

Under the proposed change, permit and LOC holders would still be subject to agency oversight. For example, permit and LOC holders must submit annual reports as required by the regulations at § 216.38 and § 216.45(d)(2), respectively. This requirement is universal, regardless of how long their permit or LOC is valid. Further, permit holders are required to stop permitted activities and submit incident reports for incidents such as mortalities, exceeding authorized take, and taking protected species that were not authorized. LOC and photography permit holders must temporarily stop authorized research if they exceed Level B harassment. Annual and incident reports allow NMFS to monitor permit and LOC compliance and impacts to protected species and are available to the public. NMFS would maintain its authority for permit or LOC modification, suspension, or revocation. For example, NMFS may determine a permit modification is warranted to add permit restrictions in response to information provided in annual or incident reports.

For any amendment to a permit, or change to an LOC, the agency would reexamine the NEPA analysis based on information provided in the amendment request, taking into consideration information in annual and incident reports and in published literature.

Likewise, if ESA listed species are involved and the action is covered under an ESA section 7 consultation and, for example, a new species is listed or critical habitat is designated, NMFS would review the new information to determine if consultation needs to be reinitiated in accordance with 50 CFR 402.16. If these analyses produce new information that would warrant a change to a permit or permits, NMFS retains the ability to amend permits to add permit conditions, such as mitigation measures to minimize impacts to protected species, as described in § 216.36(b).

Amendments To Extend the Permit or LOC Duration

For amendments that extend the duration of individual permits or LOCs, the process would work as it does now under the regulations, but without the 5-year limit. Any extension of a permit by more than 12 months would still be considered a major amendment requiring public comment. Permit holders may continue to request a minor amendment to extend the duration of their permit up to 1 year, if justified. The agency would continue to publish in the **Federal Register** notices of receipt of requests for major amendments for a 30-day public comment period, and notices of issuance of minor amendments extending a permit up to 1 year.

Classification

Pursuant to the procedures established to implement Executive Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. Permit and LOC applicants including individuals, academic institutions, business or other for-profit organizations, not-for-profit institutions, and government organizations are the only entities that would be subject to the requirements in these proposed regulations. The number of small governmental jurisdictions, small organizations, or small businesses affected is approximately less than 150 entities total, and less than 35 annually. The change in duration of permits would not affect the cost to these small entities, as it would require the same amount of time and resources to apply for a 5-year permit as it would to apply for a permit of a longer duration. Overall, this rule may reduce the costs to these entities because they would spend less time applying for permits. For example, the estimated number of burden hours to complete a scientific research permit application is 50 hours, with an estimated average hourly rate of $32.58. Thus, an applicant for a scientific research permit would spend approximately $3,258 and 100 hours to apply for two consecutive 5-year research permits. If the duration limit for special exception permits is removed, the number of burden hours and costs to apply for a scientific research permit could be reduced to approximately $1,629 and 50 hours for a 10-year permit, if issued. A longer duration permit would save additional costs. An applicant for a General Authorization LOC would spend approximately 10 hours and $325.80 to complete a 5-year LOC application, which if issued for a longer period, would reduce that cost. Because of this, a regulatory flexibility analysis is not required, and none has been prepared.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number. This proposed rule contains collection-of-information requirements subject to the provisions of the PRA.[1] No changes to the reporting requirements or to the information collection instrument is required as a result of this regulatory change, other than removing the 5-year duration restriction.

[1] The information collection is currently approved by OMB under control no. 0648–0084, *Basic Requirements for Special Exception Permits and Authorizations to Take, Import, and Export Marine Mammals, Threatened and Endangered Species, and for Maintaining a Captive Marine Mammal Inventory Under section 104 of the MMPA, the Fur Seal Act, and/or section 10(a)(1)(A) of the Endangered Species Act.*

List of Subjects in 50 CFR Part 216

Regulations governing the taking and importing of marine mammals.

Dated: April 24, 2024.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 216 is proposed to be amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

* * * * *

■ 2. In § 216.35, revise paragraph (b) to read as follows:

§ 216.35 Permit restrictions.

* * * * *

(b) Special exception permits expire on the date specified in the permit, unless limited or extended in duration by the Director in accordance with § 216.36 and § 216.39.

* * * * *

■ 3. In § 216.45, revise paragraph (b)(2)(iv) and paragraph (d)(3) to read as follows:

§ 216.45 General Authorization for Level B harassment for scientific research.

* * * * *

(b) * * *

(2) * * *

(iv) The period of time over which the research project or program will be conducted (*i.e.,* the requested period of the LOC), including the field season(s) for the research, if applicable;

* * * * *

(d) * * *

(3) Authorization to conduct research under the General Authorization is for the period(s) of time identified in the letter of confirmation issued under paragraph (c) of this section, unless limited or extended by the Director, or modified, suspended, or revoked in accordance with paragraph (e) of this section;

* * * * *

[FR Doc. 2024–09258 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 89, No. 86
Thursday, May 2, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Meeting

AGENCY: Agency for International Development.

ACTION: Request for public comment and notice of public meeting.

SUMMARY: The United States Agency for International Development (USAID) announces a public meeting, and requests public comment for the fourth meeting of the Partnership for Peace Fund (PPF) Advisory Board to receive updates on progress and changes to USAID programming under MEPPA following the terrorist attacks of October 7, 2023, and discuss recommendations for the strategic direction of MEPPA in this new context.

DATES: Written comments and information are requested on or before May 16, 2024, at 5:00 p.m. EST.

The public meeting will take place on Tuesday, May 21, 2024, from 9:00 a.m.–11:15 a.m. EST via the Zoom platform (*https://usaid.zoomgov.com/j/1606503264?pwd=ZVpXSWpnYnBoTHFIVFEwYTR5QTVTUT09*).

The meeting does not require pre-registration.

ADDRESSES: You may submit comments regarding the work of the PPF Advisory Board by email to *MEPPA@usaid.gov.* Include ''Public Comment, PPF Advisory Board Meeting, May 21'' in the subject line. All public comments and questions will be included in the official record of the meeting and posted publicly on the USAID website.

Please email *MEPPA@usaid.gov* to request reasonable accommodations for the public meeting. Include ''Request for Reasonable Accommodation, PPF Advisory Board Meeting, May 21'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Dan McDonald, 202–712–4965, *meppa@usaid.gov*.

SUPPLEMENTARY INFORMATION: In December 2020, Congress passed the Nita M. Lowey Middle East Partnership for Peace Act, or MEPPA, with bipartisan support. The Act directs USAID and the U.S. International Development Finance Corporation (DFC), in coordination with the Department of State, to program $250 million over five years to build the foundation for peaceful coexistence between Israelis and Palestinians through a new PPF, managed by USAID, and a Joint Investment Initiative, managed by the DFC.

MEPPA serves as a recognition that economic, social, and political connections between Israelis and Palestinians are the best way to foster mutual understanding and provide the strongest basis for a sustainable, two-state solution. USAID's Middle East Bureau has been working with Congress, interagency colleagues, and partners in Israel, the West Bank, and Gaza to implement the Act. MEPPA also calls for the establishment of a board to advise USAID on the strategic direction of the PPF.

Composed of up to 15 members, the PPF Advisory Board includes development experts, private sector leaders and faith-based leaders who are appointed by members of Congress and the USAID Administrator. As stated in its charter, the Board's role is purely advisory and possesses no enforcement authority or power to bind USAID. Duties of the Board and individual members are restricted to providing information and making recommendations to USAID on matters and issues relating to the types of projects USAID should seek to support in order to further the purposes of the People-to-People Partnership for Peace Fund and partnerships with foreign governments and international organizations to leverage the impact of the People-to-People Partnership for Peace Fund.

The following are the current members of the Advisory Board:

Chair: The Honorable George R. Salem
The Honorable Elliott Abrams
Farah Bdour
Rabbi Angela Buchdahl
Rabbi Michael M. Cohen
Sander Gerber
Ambassador Mark Green (ret.)
Hiba Husseini
Heather Johnston
Harley Lippman
The Honorable Nita M. Lowey
Dina Powell McCormick
Nickolay Mladenov
Jen Stewart
The Honorable Robert Wexler

PPF Advisory Board meetings are held twice a year and are public. More information about how USAID is implementing MEPPA to increase people-to-people partnerships between Israelis and Palestinians is available at: *https://www.usaid.gov/west-bank-and-gaza/meppa*.

The purpose of this meeting is for the Advisory Board to gain a better understanding of the progress so far to program funds under the PPF to bring Israelis and Palestinians together to increase understanding and advance the goal of a two-state solution.

During this meeting, the Board will (1) receive updates on progress and changes to USAID programming under MEPPA following the terrorist attacks of October 7, 2023, and (2) discuss recommendations for the strategic direction of MEPPA in this new context.

Request for Public Comment

To inform the direction and advice of the Board, USAID invites written comments from the public on areas for focus and strategies for people-to-people peacebuilding under the PPF.

Written comments and information are requested on or before Thursday, May 16, 2024, at 5:00 p.m. EDT. Include ''Public Comment, PPF Advisory Board Meeting, May 21'' in the subject line. Please submit comments and information as a Word or PDF attachment to your email. You are encouraged to submit written comments even if you plan to attend the public meeting. All public comments and questions will be included in the official record of the meeting and posted publicly on the USAID website.

Public Meeting

A public meeting will take place Tuesday, May 21, 2024, from 9:00 a.m.–11:15 a.m. This meeting is free and open to the public. Persons wishing to attend the meeting should use the following link: (*https://usaid.zoomgov.com/j/1606503264?pwd=ZVpXSWpnYnBoTHFIVFEwYTR5QTVTUT09*).

Requests for reasonable accommodations should be directed to

Daniel McDonald at *MEPPA@usaid.gov.* Please include ''Request for Reasonable Accommodation, PPF Advisory Board Meeting, May 21'' in the subject line.

Daniel McDonald,

USAID Designated Federal Officer for the PPF Advisory Board, Bureau for the Middle East, U.S. Agency for International Development.

[FR Doc. 2024–09503 Filed 5–1–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Tribal Advisory Committee

AGENCY: Office of Tribal Relations, USDA.

ACTION: Notice of public, hybrid meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the US Department of Agriculture (USDA) and the Federal Advisory Committee Act (FACA), the Office of Tribal Relations is announcing a meeting of the Tribal Advisory Committee. The committee is authorized under the Agriculture Improvement Act of 2018 (the 2018 Farm Bill) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to provide advice and guidance to USDA on matters related to Tribal and Indian affairs.

DATES: An in-person meeting with a virtual webinar with a call-in option will be held on Wednesday, May 29, 2024, from 9:00 a.m. to approximately 5:00 p.m. Eastern Time (ET), as well as Thursday, May 30, 2024, from 9:00 a.m. to approximately 12: 00 p.m. ET. The meeting will be held in the Lincoln Room of the USDA Whitten Building; 1400 Jefferson Avenue SW, Washington, DC 20250. Because this meeting will be hosted in a secured facility, members of the public wishing to attend in-person must register in advance.

Webinar Participation Information: Registration to attend this meeting, including to provide oral public comments, is available at *https://www.zoomgov.com/webinar/register/WN_KUUOcnuqSLGM0Ly7QVjKTQ*.

Public Comments: The public may file written comments to the Tribal Advisory Committee by May 13, 2024, via email at *Tribal.Relations@usda.gov*. While other comments will be included in the public record for this meeting, the Committee may not have time to deliberate on comments received at this date during this meeting.

Register for the Meeting: Because this meeting is hosted in a public facility, registration for in-person attendance will be required by Wednesday, May 22, 2024. Your pre-registration must state: the names of each person in your group; organization or interest represented; the number of people planning to give oral comments, if any; and whether anyone in your group requires special accommodations. Please submit registrations for in-person attendance to *https://forms.office.com/g/YECzJvSTcr* by May 22, 2024. Registration for virtual attendance must be submitted at *https://www.zoomgov.com/webinar/register/WN_KUUOcnuqSLGM0Ly7QVjKTQ* by May 22, 2024.

FOR FURTHER INFORMATION CONTACT: General information about the committee can also be found at *https://www.usda.gov/tribalrelations/advisory-committee*. Josiah Griffin, Designated Federal Officer, by phone at 202–689–4861 or via email at *Josiah.Griffin@usda.gov*.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: This meeting will be the second convening of the Tribal Advisory Committee. An agenda and more information for this meeting will be available at *https://www.usda.gov/tribalrelations/advisory-committee*.

The Secretary establishes the Committee pursuant to section 12303 of the Agriculture Improvement Act of 2018 (7 U.S.C. 6921(b)) and will be managed in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 10. Under the law, the Secretary of Agriculture appointed three members, and the Chair and Ranking Members of the House Committee on Agriculture and the Senate Committees on Indian Affairs and Agriculture, Nutrition, and Forestry appointed the remaining eight members. In addition to providing recommendations to the Secretary, the Tribal Advisory Committee is required to provide a report to the three Congressional Committees listed above.

Register for the Meeting: Because this meeting is hosted in a secured public facility, registration for in-person attendance will be required by Wednesday, May 22, 2024. Your pre-registration must state: the names of each person in your group; organization or interest represented; the number of people planning to give oral comments, if any; and whether anyone in your group requires special accommodations. Please submit registrations for in-person attendance to *https://forms.office.com/g/YECzJvSTcr* by May 22, 2024. Registration for virtual attendance must be submitted at *https://www.zoomgov.com/webinar/register/WN_KUUOcnuqSLGM0Ly7QVjKTQ* by May 22, 2024.

Public Comment: Members of the public are invited to join the Tribal Advisory Committee meeting in listen only mode each day and will be invited to give oral comments to the Committee from 3:00 p.m. ET to 4:00 p.m. ET on Wednesday, May 29, 2024. Members of the public who request to give oral comments to the Committee, must arrive by 3:00P.M. Eastern Time (ET) on May 29, 2024, and will be given no more than five (5) minutes to provide oral comment.

Availability of Materials for the Meeting: All written public comments will be compiled into a binder and available for review at the meeting. Duplicate comments from multiple individuals will appear as one comment, with a notation that multiple copies of the comment were received. Please visit *https://www.usda.gov/tribalrelations/advisory-committee* to learn more about the agenda for or reports resulting from this meeting. Please be advised that anyone calling into the Zoom teleconference system or participating in-person that is interested in providing public comment will be asked to provide their names, their title, and their tribal or organizational affiliations. Callers can expect to incur charges for calls they initiate over wireless lines, and the USDA will not refund any incurred charges.

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may

be made available in languages other than English.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken in account the needs of the diverse groups served by USDA, membership shall include to the extent possible, individuals with demonstrated ability to represent minorities, women and person with disabilities. USDA is an equal opportunity provider, employer, and lender.

Dated: April 22, 2024.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2024–09465 Filed 5–1–24; 8:45 am]

BILLING CODE 3420–AG–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by June 3, 2024 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Consumer Labeling Research: Web-Based Experimental Survey.

OMB Control Number: 0583–NEW.

Summary of Collection: Food Safety and Inspection Service has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled. Safe handling instructions (SHI) are required on the labels of raw or partially cooked (*i.e.,* not considered ready to eat) meat and poultry products if the product is destined for household consumers or institutional uses (9 CFR 317.2(l) and 9 CFR 381.125(b)). FSIS has required the SHI label for raw and partially cooked meat and poultry products since 1994 (59 FR 40209, August 8, 1994).

Need and Use of the Information: The web-based experimental survey will address two primary research questions (RQs): (1) Do any of the test SHI labels perform better at attracting consumer attention (*i.e.,* noticeability) relative to the current SHI label? and (2) Do any of the test SHI labels perform better at motivating consumers to follow recommend safe handling instructions relative to the current SHI label? The survey will also collect information to measure the following secondary outcomes for consumer response to the SHI label: visual receptivity, perceived risk impact (overall label and risk message on label), efficacy, comprehension, learned new information, receptivity to fear appeal messaging, and perceived likelihood of getting foodborne illness if instructions are not followed. The survey will assess consumer noticeability for alternative formats of a standardized food safety cue (in addition to the SHI label) that could be used on raw and partially cooked meat and poultry products to convey that the product is not fully cooked and requires cooking to the recommended internal temperature to ensure food safety.

This data from this collection will be used to further inform label design; provide information about how consumers use food safety information on labels and whether it would be useful to provide the minimum cooking temperature on the product, and if so, where on the product (*e.g.,* front, back, no preference), and to determine the most useful location for the SHI label (*e.g.,* front, back, no preference). The survey will also collect information on the likelihood of scanning a QR code on a package of raw meat or poultry to get more information about safe handling practices. The survey will include a question to measure awareness of the current SHI label by asking respondents to select which images they have seen before (the response options will include the current SHI label and several distractors such as the MyPlate icon).

Description of Respondents: Individuals/Households.

Number of Respondents: 50,000.

Frequency of Responses: Reporting; Other (one-time).

Total Burden Hours: 2,500.

Rachelle Ragland-Greene,

Acting Departmental Information Collection Clearance Officer.

[FR Doc. 2024–09467 Filed 5–1–24; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

Under Secretary of Economic Affairs

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Concrete Masonry Products Research, Education, and Promotion Evaluation and Compliance and Membership Application Forms

AGENCY: Under Secretary of Economic Affairs, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 1, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Kenneth White, Office of the Under Secretary of Economic Affairs, by email at *kwhite2@doc.gov* or *PRAcomments@doc.gov*. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Kenneth White, Senior Policy Analyst, Under Secretary of Economic Affairs, by mail at U.S. Department of Commerce; 1401 Constitution Avenue NW, Washington, DC or via email at *kwhite2@doc.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for an extension of an already approved collection of information. In 2021 the Secretary held a referendum among eligible manufacturers to determine whether they favored the implementation of an Order to establish an orderly program for developing, financing, and carrying out an effective, continuous, and coordinated program of promotion, education, and research to support the concrete masonry products industry. The referendum passed and the Order went into effect in December 2021. The Order requires the Secretary to establish a board to carry out the program. The Secretary appointed Board members in the Fall of 2022. (1) The Order establishes a three-year term limit for Board members, thus requiring ongoing and continuous consideration of applicants to fill vacancies. (2) The Order requires producers of concrete masonry block to remit quarterly, an assessment to the Board. Continuation of this approved collection will allow consideration of applicants to the Board to fill vacancies and allow reporting of quarterly assessment payments.

In 2022, the Secretary appointed members to the Concrete Masonry Products Board (Board) to develop and implement programs of research, education, and promotion. In 2023 the Board began collecting assessments from manufacturers of concrete masonry units, of which the Board will use to implement programs and activities.

There are two forms in this Information Collection Request (ICR) relating to the Board membership and the collection of assessments. The first is the application form to be considered for Board membership. Board membership is open to all manufacturers of concrete masonry products. Completion of the application form reflects an individual's interest in becoming a Board member and is necessary to verify eligibility and to assist in determining suitability to serve on the Board. The second form for this ICR relates to the payment of assessments. Producers that remit assessments will complete the form to establish proper payment of assessments. Authorizing Statute: 15 U.S.C. Chapter 13 (sections 8701–8717).

II. Method of Collection

Registrants may download, complete, print, and submit via fax or mail from the Board's website.

III. Data

OMB Control Number: 0605–0028.

Form Number(s): None.

Type of Review: Regular submission. This is an extension.

Affected Public: Business or other for-profit organizations.

Board Application

Estimate of Burden: 0.25 hour per application.

Respondents: Manufacturers of concrete masonry units.

Estimated Number of Respondents: 160.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 40 hours.

Respondents Obligation: Voluntary.

Evaluation and Compliance

Estimate of Burden: 0.5 hour per quarterly report.

Respondents: Manufacturers of concrete masonry units.

Estimated Number of Respondents: 160.

Estimated Number of Responses per Respondent: 4.

Estimated Total Annual Burden on Respondents: 320 hours.

Respondent's Obligation: Mandatory.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09481 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Direct Investment Surveys: BE–10, Benchmark Survey of U.S. Direct Investment Abroad

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 1, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Kirsten Brew, Chief, Multinational Operations Branch, Bureau of Economic Analysis, U.S. Department of Commerce, by email to *Kirsten.Brew@bea.gov* and *PRAcomments@bea.gov*. Please reference OMB Control Number 0608–0049 in the subject line of your comments. Do not submit Confidential

Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Kirsten Brew, Chief, Multinational Operations Branch, Bureau of Economic Analysis, U.S. Department of Commerce; by mail at 4600 Silver Hill Rd, Suitland, MD 20746 or via email at *Kirsten.Brew@bea.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Benchmark Survey of U.S. Direct Investment Abroad (BE- 10) obtains data on the financial structure and operations of U.S. parents and their foreign affiliates. The data are needed to provide reliable, useful, and timely measures of U.S. direct investment abroad, measure changes in such investment, and assess its impact on the U.S. and foreign economies. Such data are generally found in enterprise-level accounting records of respondent companies. The benchmark data provide a baseline for subsequent sample-based estimates in non-benchmark years. In particular, they serve as benchmarks for the quarterly direct investment estimates included in the U.S. international transactions, international investment position, and national income and product accounts, and for annual estimates of the U.S. direct investment abroad position and of the activities of U.S. multinational enterprises. The data collected include balance sheets; income statements; property, plant, and equipment; employment and employee compensation; merchandise trade; sales of goods and services; taxes; and research and development activity.

The Bureau of Economic Analysis (BEA) proposes the following changes:

Data items to be added:

Employment—A question will be added to the Employment section of the BE–10A form to collect data on employees who are on the payroll of the U.S. company but live overseas on a permanent basis. This would include full and part-time employees that work for a foreign affiliate but are paid by the U.S. parent company, and those employees that were hired, or moved, abroad to fill a remote-work position offered by the U.S. parent.

Equity investment—A question will be added to the Assets section of the BE–10C form to collect equity investment in other foreign affiliates, consistent with the BE–10B form.

Data items to be modified:

Supplement A—Will be modified on the BE–10B and C forms to offer more options for the reasons the foreign business enterprises changed since last reported, such as options for ''acquired'' or ''established'' if it is a ''new'' enterprise, and to identify the date of the transaction for new enterprises.

Advertising—Question 109 which collects advertising sales data on the BE–10B form will be expanded to capture additional sales detail by affiliated and unaffiliated customer.

Digital economy—Questions on services provided via digital intermediation platforms collected on the BE–10A (items 60–62) and BE–10B (item 108), and questions on digital delivery and digital ordering collected on the BE–10A (items 63–65) and BE–10B forms (items 110–112) will be modified to more accurately reflect terminology used by BEA survey respondents, and to reflect updates to the definitions of digitally ordered and delivered in the Handbook on Measuring Digital Trade (second edition) jointly authored by the International Monetary Fund, the Organisation for Economic Cooperation and Development, the World Trade Organization, and the United Nations Conference on Trade and Development.

II. Method of Collection

This survey is a benchmark survey, or census. The potential respondent universe for the 2024 Benchmark Survey of U.S. Direct Investment Abroad, BE–10, consists of all U.S. persons (in the broad legal sense, including companies) that own 10 percent or more of the voting securities of an incorporated foreign business enterprise, or an equivalent interest in an unincorporated foreign business enterprise. Persons subject to the reporting requirements of the BE–10, Benchmark Survey of U.S. Direct Investment Abroad, would be required to respond, whether or not they are contacted by BEA.

BEA will provide respondents with advance notice of the survey by mailing them an announcement of the upcoming survey as soon as possible after the survey has been approved by OMB. Later, in March, respondents will receive notification by mail of their obligation to file; responses covering a reporting company's fiscal year ending during the previous calendar year are due by May 31.

BEA offers electronic filing through its eFile system for use in reporting on the BE–10 annual survey forms. In addition, BEA posts all its survey forms and reporting instructions on its website (*www.bea.gov/dia*). These may be downloaded, completed, printed, and submitted via fax or mail.

III. Data

OMB Control Number: 0608–0049.

Form Number: BE–10.

Type of Review: Revision.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 29,000 respondents (U.S. parents). A complete response includes a BE–10 A form for the U.S. parent's domestic operation and one or more BE–11 B, C, or D forms for its foreign affiliates that meet the BE–11 survey requirements. BEA estimates that U.S. parents will submit 29,000 A forms, 20,100 B forms, 15,500 C forms, 29,000 D forms, and 1,700 Claim for Exemption forms.

Estimated Total Annual Burden Hours: 842,700 hours. Total annual burden is calculated by multiplying the estimated number of submissions of each form by the average hourly burden per form, which is 11 hours for the A form, 19 hours for the B form, 6 hours for the C form, 2 hours for the D form, and .5 hours for the Claim for Not Filing form.

Estimated Time per Respondent: 29 hours per respondent (842,700 hours/29,000 U.S. parents) is the average but may vary considerably among respondents because of differences in company structure, complexity, and the number of foreign affiliates each U.S. parent must report.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (P.L. 94–472, 22 U.S.C. 3101–3108, as amended).

IV. Request for Comments

We are soliciting public comments to permit the Department of Commerce/Bureau of Economic Analysis to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before

including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09482 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the U.S. Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to: (a) identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to Request a Review: Not later than the last day of May 2024,[2]

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in May for the following periods:

	Period to be reviewed
Antidumping Duty Proceedings	
AUSTRIA: Carbon and Alloy Steel Cut-To-Length Plate, A–433–812	5/1/23–4/30/24
BELGIUM:	
Carbon and Alloy Steel Cut-To-Length Plate, A–423–812	5/1/23–4/30/24
Stainless Steel Plate in Coils, A–423–808	5/1/23–4/30/24
BRAZIL: Iron Construction Castings, A–351–503	5/1/23–4/30/24
CAMBODIA: Mattresses, A–555–001	5/1/23–4/30/24
CANADA:	
Large Diameter Welded Pipe, A–122–863	5/1/23–4/30/24
Polyethylene Terephthalate Resin, A–122–855	5/1/23–4/30/24
FRANCE:	
Carbon and Alloy Steel Cut-To-Length Plate, A–427–828	5/1/23–4/30/24
Certain Preserved Mushrooms,[3] A–427–833	9/13/22–12/31/23
GERMANY: Carbon and Alloy Steel Cut-To-Length Plate, A–428–844	5/1/23–4/30/24
GREECE: Large Diameter Welded Pipe, A–484–803	5/1/23–4/30/24
INDIA:	
Certain Welded Carbon Steel Standard Pipes and Tubes, A–533–502	5/1/23–4/30/24
Organic Soybean Meal, A–533–901	5/1/23–4/30/24
Polyethylene Terephthalate Resin, A–533–861	5/1/23–4/30/24
Silicomanganese, A–533–823	5/1/23–4/30/24
INDONESIA:	
Mattresses, A–560–836	5/1/23–4/30/24
Polyethylene Retail Carrier Bags, A–560–822	5/1/23–4/30/24
ITALY:	
Carbon and Alloy Steel Cut-To-Length Plate, A–475–834	5/1/23–4/30/24
Carbon and Alloy Steel Wire Rod, A–475–836	5/1/23–4/30/24
JAPAN:	
Carbon and Alloy Steel Cut-To-Length Plate, A–588–875	5/1/23–4/30/24
Diffusion-Annealed Nickel-Plated Flat-Rolled Steel Products, A–588–869	5/1/23–4/30/24
Gray Portland Cement and Cement Clinker, A–588–815	5/1/23–4/30/24
KAZAKHSTAN: Silicomanganese, A–834–807	5/1/23–4/30/24
MALAYSIA: Mattresses, A–557–818	5/1/23–4/30/24,
NETHERLANDS: Certain Preserved Mushrooms, A–421–815	11/3/22–4/30/24
OMAN: Polyethylene Terephthalate Resin, A–523–810	5/1/23–4/30/24
POLAND: Certain Preserved Mushrooms, A–455–806	11/3/22–4/30/24
REPUBLIC OF KOREA:	
Carbon and Alloy Steel Cut-To-Length Plate, A–580–887	5/1/23–4/30/24
Carbon and Alloy Steel Wire Rod, A–580–891	5/1/23–4/30/24
Ferrovanadium, A–580–886	5/1/23–4/30/24
Large Diameter Welded Pipe, A–580–897	5/1/23–4/30/24
Polyester Staple Fiber, A–580–839	5/1/23–4/30/24
SERBIA: Mattresses, A–801–002	5/1/23–4/30/24
SOCIALIST REPUBLIC OF VIETNAM:	
Polyethylene Retail Carrier Bags, A–552–806	5/1/23–4/30/24
Mattresses, A–552–827	5/1/23–4/30/24
SOUTH AFRICA: Stainless Steel Plate in Coils, A–791–805	5/1/23–4/30/24
SPAIN:	
Carbon and Alloy Steel Wire Rod, A–469–816	5/1/23–4/30/24
Certain Preserved Mushrooms, A–469–825	11/3/22–4/30/24,
TAIWAN:	
Carbon and Alloy Steel Cut-To-Length Plate, A–583–858	5/1/23–4/30/24
Certain Circular Welded Carbon Steel Pipes and Tubes, A–583–008	5/1/23–4/30/24
Polyester Staple Fiber, A–583–833	5/1/23–4/30/24
Polyethylene Retail Carrier Bags, A–583–843	5/1/23–4/30/24
Certain Stainless Steel Plate in Coils, A–583–830	5/1/23–4/30/24
THAILAND: Mattresses, A–549–841	5/1/23–4/30/24
THE PEOPLE'S REPUBLIC OF CHINA:	
1-Hydroxyethylidene-1, 1-Diphoshonic Acid (HEDP), A–570–045	5/1/23–4/30/24
Aluminum Extrusions, A–570–967	5/1/23–4/30/24
Carton-Closing Staples, A–570–055	5/1/23–5/7/24
Cast Iron Soil Pipe, A–570–079	5/1/23–4/30/24,
Certain Steel Wheels, A–570–082	5/1/23–4/30/24
Certain Vertical Shaft Engines Between 99cc and Up to 225cc, and Parts Thereof, A–570–124	5/1/23–4/30/24
Circular Welded Carbon Quality Steel Line Pipe, A–570–935	5/1/23–4/30/24

[3] This case was listed in the January opportunity notice with an incorrect period of review. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List,* 89 FR 63, 64 (January 2, 2024). We are hereby correcting this error and providing interested parties with an opportunity to request a review for the corrected period of review by not later than the last day of May 2024.

	Period to be reviewed
Citric Acid and Citrate Salt, A–570–937	5/1/23–4/30/24
Iron Construction Castings, A–570–502	5/1/23–4/30/24
Non-refillable Steel Cylinders, A–570–126	5/1/23–4/30/24
Oil Country Tubular Goods, A–570–943	5/1/23–4/30/24
Polyethylene Terephthalate Resin, A–570–024	5/1/23–4/30/24
Pure Magnesium, A–570–832	5/1/23–4/30/24
Stilbenic Optical Brightening Agents, A–570–972	5/1/23–4/30/24
Walk-Behind Snow Throwers and Parts Thereof, A–570–141	5/1/23–4/30/24
REPUBLIC OF TÜRKIYE:	
Carbon and Alloy Steel Wire Rod, A–489–831	5/1/23–4/30/24
Circular Welded Carbon Steel Pipes and Tubes, A–489–501	5/1/23–4/30/24
Large Diameter Welded Pipe, A–489–833	5/1/23–4/30/24
Light-Walled Rectangular Pipe and Tube, A–489–815	5/1/23–4/30/24
Mattresses, A–489–841	5/1/23–4/30/23
UNITED ARAB EMIRATES: Steel Nails, A–520–804	5/1/23–4/30/24
THE UNITED KINGDOM: Carbon and Alloy Steel Wire Rod, A–412–826	5/1/23–4/30/24
VENEZUELA: Silicomanganese, A–307–820	5/1/23–4/30/24
Countervailing Duty Proceedings	
BRAZIL: Heavy Iron Construction Castings, C–351–504	1/1/23–12/31/23
INDIA:	
Organic Soybean Meal, C–533–902	1/1/23–12/31/23
Polyethylene Terephthalate Resin, C–533–862	1/1/23–12/31/23
ITALY: Carbon and Alloy Steel Wire Rod, C–475–837	1/1/23–12/31/23
REPUBLIC OF KOREA:	
Carbon and Alloy Steel Cut-To-Length Plate, C–580–888	1/1/23–12/31/23
Large Diameter Welded Pipe, C–580–898	1/1/23–12/31/23
SOCIALIST REPUBLIC OF VIETNAM: Polyethylene Retail Carrier Bags, C–552–805	1/1/23–12/31/23
SOUTH AFRICA: Stainless Steel Plate in Coils, C–791–806	1/1/23–12/31/23
THE PEOPLE'S REPUBLIC OF CHINA:	
1-Hydroxyethylidene-1, 1-Diphoshonic Acid (HEDP), C–570–046	1/1/23–12/31/23
Aluminum Extrusions, C–570–968	1/1/23–12/31/23
Mattresses, C–570–128	1/1/23–12/31/23
Cast Iron Soil Pipe, C–570–080	1/1/23–12/31/23
Certain Chassis and Subassemblies Thereof, C–570–136	1/1/23–12/31/23
Certain Steel Wheels, C–570–083	1/1/23–12/31/23
Certain Vertical Shaft Engines Between 99cc and Up to 225cc, and Parts Thereof, C–570–125	1/1/23–12/31/23
Citric Acid and Citrate Salt, C–570–938	1/1/23–12/31/23
Non-refillable Steel Cylinders, C–570–127	1/1/23–12/31/23
Polyethylene Terephthalate Resin, C–570–025	1/1/23–12/31/23
Walk-Behind Snow Throwers and Parts Thereof, C–570–142	1/1/23–12/31/23
REPUBLIC OF TÜRKIYE:	
Carbon and Alloy Steel Wire Rod, C–489–832	1/1/23–12/31/23
Large Diameter Welded Pipe, C–489–834	1/1/23–12/31/23
Suspension Agreements	
None.	

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of

merchandise subject to antidumping findings and orders.[4]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[5] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[6] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov*.[7] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[8]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of May 2024. If Commerce does not receive, by the last day of May 2024,[9] a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

Establishment of and Updates to the Annual Inquiry Service List

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[10] On September 27, 2021, Commerce also published the notice entitled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[11] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[12]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** before November 4, 2021, Commerce created an annual inquiry service list segment for each order and suspended investigation. Interested parties who wished to be added to the annual inquiry service list for an order submitted an entry of appearance to the annual inquiry service list segment for the order in ACCESS, and on November 4, 2021, Commerce finalized the initial annual inquiry service lists for each order and suspended investigation. Each annual inquiry service list has been saved as a public service list in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [13]

As mentioned in the *Procedural Guidance,* beginning in January 2022, Commerce will update these annual inquiry service lists on an annual basis when the *Opportunity Notice* for the anniversary month of the order or suspended investigation is published in the **Federal Register**.[14] Accordingly, Commerce will update the annual inquiry service lists for the above-listed antidumping and countervailing duty proceedings. All interested parties wishing to appear on the updated annual inquiry service list must take one of the two following actions: (1) new interested parties who did not previously submit an entry of appearance must submit a new entry of appearance at this time; (2) interested parties who were included in the preceding annual inquiry service list must submit an amended entry of appearance to be included in the next year's annual inquiry service list. For these interested parties, Commerce will

[4] *See* the Enforcement and Compliance website at *https://www.trade.gov/us-antidumping-and-countervailing-duties.*

[5] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[6] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[7] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[8] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

[9] In the opportunity to request administrative review notice for orders, findings, or suspended investigations with April anniversary dates, Commerce inadvertently identified the deadline to request a review of covered entries as the last day of March 2024. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 89 FR 22390 (April 1, 2024). Commerce hereby corrects this date to identify the deadline to request a review of these entries as the last day of April 30, 2024.

[10] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[11] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[12] *Id.*

[13] This segment has been combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[14] *See Procedural Guidance,* 86 FR at 53206.

change the entry of appearance status from ''Active'' to ''Needs Amendment'' for the annual inquiry service lists corresponding to the above-listed proceedings. This will allow those interested parties to make any necessary amendments and resubmit their entries of appearance. If no amendments need to be made, the interested party should indicate in the area on the ACCESS form requesting an explanation for the amendment that it is resubmitting its entry of appearance for inclusion in the annual inquiry service list for the following year. As mentioned in the *Final Rule,*[15] once the petitioners and foreign governments have submitted an entry of appearance for the first time, they will automatically be added to the updated annual inquiry service list each year.

Interested parties have 30 days after the date of this notice to submit new or amended entries of appearance. Commerce will then finalize the annual inquiry service lists five business days thereafter. For ease of administration, please note that Commerce requests that law firms with more than one attorney representing interested parties in a proceeding designate a lead attorney to be included on the annual inquiry service list.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov.*

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [16] Accordingly, as stated above and pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

This notice is not required by statute but is published as a service to the international trading community.

Dated: April 26, 2024.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2024–09581 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[15] *See Final Rule,* 86 FR at 52335.

[16] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–107]

Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to producers and exporters of wooden cabinets and vanities and components thereof (wooden cabinets) from the People's Republic of China (China), during the period of review (POR) January 1, 2022, through December 31, 2022. In addition, Commerce is rescinding this review, in part, with respect to 28 companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Suresh Maniam or Michael Romani, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1603 or (202) 482–0198, respectively.

Background

On April 21, 2020, Commerce published in the **Federal Register** the countervailing duty (CVD) order on wooden cabinets from China.[1] On June 12, 2023, Commerce published in the **Federal Register** the notice of initiation of an administrative review of the *Order.*[2] On August 16, 2023, Commerce selected The Ancientree Cabinet Co., Ltd. (Ancientree) and Jiangsu Sunwell Cabinet Co. Ltd. (Sunwell) for individual examination as the mandatory respondents in this administrative review.[3] Between September 13 and October 25, 2023, multiple parties either withdrew their requests for review or did not respond to our initial questionnaire.[4] On November 13, 2023, we also selected Yixing Pengjia Cabinetry Co., Ltd. for individual examination as a mandatory respondent.[5] During the course of this proceeding, Yixing Pengjia Cabinetry Co., Ltd. explained that its name changed to Yixing Pengjia Technology Co., Ltd. (Pengjia). On December 4, 2023, we extended the deadline for the preliminary results of this administrative review until April 26, 2024.[6]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[7] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The product covered by the *Order* is wooden cabinets from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found

[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Countervailing Duty Order,* 85 FR 22134 (April 21, 2020) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021, 38033 (June 12, 2023).

[3] *See* Memorandum, ''Respondent Selection,'' dated August 16, 2023.

[4] For a full description of events regarding respondent selection, *see* Memorandum ''Fourth Respondent Selection,'' dated November 13, 2023.

[5] *Id.*

[6] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated October 30, 2023.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

countervailable, Commerce preliminarily finds that there is a subsidy (*i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific).[8] For a full description of the methodology underlying our conclusions, including our reliance, in part, on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received timely-filed withdrawal of review requests for nine companies.[9] Because the withdrawal requests were timely filed and no other parties requested a review of these companies, we are rescinding this review of the *Order,* in accordance with 19 CFR 351.213(d)(1). For a list of these companies with timely-filed withdrawal of review requests, *see* Appendix II.

Based on our analysis of U.S. Customs and Border Protection (CBP) data, we determine that 19 companies had no entries of subject merchandise during the POR. On August 21, 2023, we notified parties of our intent to rescind the administrative review with respect to 19 companies because there are no reviewable suspended entries.[10] No parties commented on the notification of intent to rescind the review, in part. Pursuant to 19 CFR 351.213(d)(3), we are rescinding the administrative review of these companies. For additional information regarding this determination, *see* the Preliminary Decision Memorandum. For a list of these companies with no reviewable suspended entries, *see* Appendix III.

Preliminary Rate for Non-Selected Companies Under Review

There are seven companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available. In this review, the preliminary rates calculated for Ancientree and Pengjia were above *de minimis* and not based entirely on facts available. Therefore, we are applying to the non-selected companies the average of the net subsidy rates calculated for Ancientree and Pengjia, which we calculated using the publicly-ranged sales data.[11] This methodology to establish the rate for the non-selected companies uses section 705(c)(5)(A) of the Act, which governs the calculation of the all-others rate in an investigation, as guidance. For further information on the calculation of the non-selected respondent rate, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily find that Yixing Pengjia Technology Co., Ltd.'s claim that it is the same company as Yixing Pengjia Cabinetry Co., Ltd. is supported by information on the record. For a complete description, *see* the Preliminary Decision Memorandum. Parties are invited to comment on this issue for the final results. As a result of this administrative review, we preliminarily find that the following net countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
The Ancientree Cabinet Co., Ltd	14.23
Yixing Pengjia Technology Co., Ltd.[12]	0.91
Jiangsu Sunwell Cabinetry Co Ltd.[13]	163.46
Taizhou Overseas Trading Company Ltd	163.46
Taishan Oversea Trading Company Ltd	163.46
Review-Specific Average Rate Applicable to the Following Companies[14]	
Fujian Dushi Wooden Industry Co., Ltd	17.20
Fuzhou CBM Import & Export Co., Ltd	17.20
KM Cabinetry Co., Ltd	17.20
Nantong Aershin Cabinet Co., Ltd	17.20
Shouguang Fushi Wood Co., Ltd	17.20
Weifang Fuxing Wood Co., Ltd	17.20
Xiamen Adler Cabinetry Co., Ltd	17.20

[8] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[9] *See* Letter on Behalf of Several Companies, ''Withdrawal of Request for Administrative Review,'' dated July 11, 2023 (on behalf of Shanghai Zifeng International Trading Co., Ltd. and Linyi Bonn Flooring Manufacture Co. Ltd.); *see also* Letter on Behalf of Several Companies, ''Withdrawal of Requests for Administrative Review,'' dated September 11, 2023.

[10] *See* Memorandum, ''Intent to Rescind Review, in Part,'' dated August 21, 2023.

[11] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts calculated in the final results of this review for the respective companies listed above, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. If the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed companies, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate (*i.e.,* 20.93 percent) [15] or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producers/exporters shown above. Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). For companies remaining under review, we intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register.** If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[16] Parties who submit case or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) a table of contents listing each issue; and (2) a table of authorities.[17]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[18] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[20] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date and time for the hearing.

Final Results

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in case briefs, within 120 days after the date of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

[12] This company was formerly known as Yixing Pengjia Cabinetry Co., Ltd. *See* Pengjia's Letter ''Section III,'' dated January 4, 2024, at 2 and Exhibit 5.1.

[13] Commerce previously found Shanghai Beautystar Cabinetry Co., Ltd. to be a cross-owned affiliate with Jiangsu Sunwell Cabinetry Co Ltd. *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Administrative Review in Part, and Intent To Rescind in Part; 2021,* 88 FR 29084 (May 5, 2023), and accompanying Preliminary Decision Memorandum at 33, unchanged in *Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Final Results and Partial Recission of Countervailing Duty Administrative Review,* 2021, 88 FR 76732 (November 7, 2023).

[14] This rate is based on the rate for the respondents that were selected for individual review, excluding rates that are zero, *de minimis,* or based entirely on facts available. *See* section 705(c)(5)(A) of the Act.

[15] *See Order,* 85 FR at 22135.

[16] *See* 19 CFR 351.309(d).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[19] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023).

[20] *See* 19 CFR 351.310(c).

VII. Use of Facts Available and Application of Adverse Inferences
VIII. Subsidies Valuation
IX. Interest Rate, Discount Rate, Input, Electricity, and Land Benchmarks
X. Analysis of Programs
XI. Recommendation

Appendix II

List of Companies Which Timely Withdrew Requests for Review

1. Shanghai Zifeng International Trading Co., Ltd.
2. Linyi Bonn Flooring Manufacture Co. Ltd.
3. Linyi Bomei Furniture Co., Ltd.
4. Honsoar New Building Material Co., Ltd.
5. Qingdao Shousheng Industry Co., Ltd.
6. Jiang Su Rongxin Wood Industry Co., Ltd.
7. Weifang Yuanlin Woodenware Co., Ltd.
8. Morewood Cabinetry Co., Ltd.
9. Pizhou Ouyme Import & Export Trade Co., Ltd.

Appendix III

List of Companies Which Did Not Have Reviewable Entries During the POR

1. Changyi Zhengheng Woodwork Co. Ltd.
2. Dalian Hualing Wood Co., Ltd.
3. Dalian Meisen Woodworking Co. Ltd. and Dalian Hechang Technology Development Co., Ltd.
4. Fujian Leifeng Cabinetry Co., Ltd.
5. Goldenhome Living Co. Ltd.
6. Guangzhou Nuolande Import and Export Co., Ltd.
7. Jiangsu Beichen Wood Co., Ltd.
8. Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
9. Linyi Kaipu Furniture Co., Ltd.
10. Senke Manufacturing Company
11. Shandong Jinhua Wood Co., Ltd.
12. Shandong Longsen Woods Co., Ltd.
13. Suofeiya Home Collection Co., Ltd.
14. Taishan Hongxiang Trading Co., Ltd.
15. Xuzhou Yihe Wood Co., Ltd.
16. Zaozhuang New Sharp Import & Export Trading Co., Ltd.
17. Zhangzhou OCA Furniture Co., Ltd.
18. Zhongshan NU Furniture Co., Ltd.
19. Zhoushan For-Strong Wood Co. Ltd.

Appendix IV

List of Non-Selected Companies Subject to This Administrative Review

1. Fujian Dushi Wooden Industry Co., Ltd.
2. Fuzhou CBM Import & Export Co., Ltd.
3. KM Cabinetry Co., Ltd.
4. Nantong Aershin Cabinet Co., Ltd
5. Shouguang Fushi Wood Co., Ltd
6. Weifang Fuxing Wood Co., Ltd.
7. Xiamen Adler Cabinetry Co., Ltd.

[FR Doc. 2024–09579 Filed 5–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–106]

Wooden Cabinet and Vanities and Components Thereof From the People's Republic of China: Preliminary Results, Preliminary Determination of No Shipments, and Partial Rescission of the Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers and/or exporters did not make sales of wooden cabinets and vanities and components thereof (wooden cabinets) from the People's Republic of China at less than normal value (NV) during the period of review (POR) April 1, 2022, through March 31, 2023. In addition, Commerce preliminarily determines that 30 companies are eligible for a separate rate and 12 companies had no shipments of subject merchandise during the POR. Further, Commerce is rescinding this review with respect to two companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Garry Kasparov, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1397.

SUPPLEMENTARY INFORMATION:

Background

On April 21, 2020, Commerce published in the **Federal Register** the antidumping duty (AD) order on wooden cabinets from China.[1] On June 12, 2023, Commerce initiated an administrative review of the *Order*.[2]

On September 25, 2023, Commerce selected Ancientree and Jiangsu Sunwell Cabinetry Co., Ltd. (Sunwell) as the mandatory respondents.[3] On September 27, 2023, Commerce issued the initial AD questionnaire to Ancientree and Sunwell.[4] Sunwell failed to respond to the initial questionnaire by the deadline. Consequently, on November 17, 2023, Commerce selected Jiangsu Weisen Houseware Co., Ltd. (Weisen) as a mandatory respondent.[5] On November 30, 2023, Commerce extended the deadline for the preliminary results of this administrative review until April 26, 2024.[6]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[7] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The merchandise covered by the *Order* is wooden cabinets from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Because China is a non-market economy (NME) country within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

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[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 85 FR 22126 (April 21, 2020) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021, 38033 (June 12, 2023).

[3] *See* Memorandum, ''Respondent Selection,'' dated September 25, 2023 (Respondent Selection Memorandum).

[4] *See* Commerce's Letters, ''Initial Questionnaire,'' dated September 27, 2023 (Initial AD Questionnaire).

[5] *See* Memorandum, ''Second Respondent Selection,'' dated November 17, 2023 (Second Respondent Selection Memorandum).

[6] *See* Memorandum ''Extension of Deadline for Preliminary Results,'' dated November 30, 2023.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, and Rescission, in Part, 2022–2023: Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Preliminary Determination of No Shipments

Based on information on the record, Commerce preliminarily determines that 12 companies subject to this administrative review had no shipments of subject merchandise during the POR.[8] Commerce is not rescinding this review with respect to these companies but, rather, intends to complete the review and issue appropriate instructions to U.S. Customs and Border Protection (CBP) based on the final results of the review.[9] For additional information regarding these preliminary determinations of no shipments, *see* the Preliminary Decision Memorandum.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws its request within 90 days of the date of publication of the notice of initiation. The requests for an administrative review of two companies, Suofeiya Home Collection Co., Ltd., and Linyi Bonn Flooring Manufacture Co., Ltd., were timely withdrawn within 90 days of the date of publication of the *Initiation Notice*.[10] As a result, Commerce is rescinding this review with respect to both companies in accordance with 19 CFR 351.213(d)(1).

Separate Rates

Commerce preliminarily determines that 30 non-individually examined companies under review are eligible for separate rates in this administrative review.[11] The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate rate respondents which Commerce did not examine individually in an administrative review. For the preliminary results of this review, Commerce has determined the estimated dumping margins for Ancientree and Weisen to be zero. For the reasons explained in the Preliminary Decision Memorandum, we are assigning this rate to the non-examined respondents which qualify for a separate rate.

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[12] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 251.64 percent) is not subject to change.[13]

For these preliminary results, Commerce preliminarily determines that 20 companies for which a review was requested, but did not file a separate rate application or demonstrate separate rate eligibility, including Sunwell, to be part of the China-wide entity.[14]

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist for the administrative review covering the period April 1, 2022, through March 31, 2023:

Exporter	Weighted-average dumping margin (percent)
Jiangsu Weisen Houseware Co., Ltd	0.00
The Ancientree Cabinet Co., Ltd	0.00
Non-Examined Companies Receiving a Separate Rate[15]	0.00

Disclosure and Public Comment

Commerce will disclose to parties to this proceeding the calculations performed for these preliminary results within five days after public announcement of the preliminary results or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, pursuant to 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[16] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[17] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their briefs that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[18] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not

[8] *See* Appendix II.

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 October 24, 2011); *see also* the ''Assessment Rates'' section, *infra.*

[10] *See* Suofeiya Home Collection Co., Ltd.'s Letter, ''Withdrawal of Request for Review,'' dated July 3, 2023, and Linyi Bonn Flooring Manufacture Co. Ltd.' Letter ''Withdrawal of Request for Administrative Review,'' dated July 11, 2023.

[11] *See* Appendix III; *see also* Preliminary Decision Memorandum at the ''Separate Rate Determination'' section for more details.

[12] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[13] *See Order.*

[14] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.''); *see also* Appendix IV for the list of companies under review that are determined to be part of the China-wide entity.

[15] *See* Appendix III.

[16] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[17] *See* 19 351.309(c)(2) and (d)(2).

[18] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[20]

Assessment Rates

Upon issuing the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[21] If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 251.64 percent to all entries of subject merchandise during the POR which were exported by the companies considered to be a part of the China-wide entity listed in Appendix IV of this notice. If Commerce determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the China-wide rate.[22]

For the companies for which Commerce is not rescinding this administrative review, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for the subject merchandise exported by the company listed above that has a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless extended, Commerce intends to issue the final results of this administrative review, which will include the results of Commerce's analysis of the issues raised in case briefs, within 120 days after the date of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during these PORs. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1)(B), 751(a)(3) and 777(i) of the Act, and 19 CFR 351.213(d)(4) and 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Companies Preliminarily Determined To Have No Shipments

1. Anhui Xinyuanda Cupboard Co., Ltd.
2. Dalian Hualing Wood Co., Ltd.
3. Dalian Meisen Woodworking Co., Ltd.
4. Dongguan Ri Sheng Home Furnishing Articles Co., Ltd.
5. Hangzhou Hoca Kitchen & Bath Products Co., Ltd.
6. Kunshan Baiyulan Furniture Co., Ltd.
7. Pizhou Ouyme Import & Export Trade Co., Ltd.
8. Quanzhou Ample Furnishings Co., Ltd.
9. Suzhou Siemo Wood Import & Export Co., Ltd.
10. Tech Forest Cabinetry Co., Ltd.
11. Weifang Fuxing Wood Co., Ltd.
12. Zhoushan For-Strong Wood Co.

Appendix III

Non-Examined Companies Under Review Receiving a Separate Rate

1. Changyi Zhengzheng Woodwork Co., Ltd.
2. Fujian Dushi Wooden Industry Co., Ltd.
3. Fujian Leifeng Cabinetry Co., Ltd.
4. Fuzhou CBM Imp & Exp Co., Ltd.
5. Goldenhome Living Co., Ltd.
6. Guangzhou Nuolande Import and Export Co., Ltd.
7. Honsoar New Building Material Co., Ltd.
8. Jiang Su Rongxin Wood Industry Co., Ltd. (Formerly known as Jiang Su Rongxin Cabinets Ltd.)
9. Jiangsu Beichen Wood Co., Ltd.
10. KM Cabinetry Co., Ltd.
11. Linyi Kaipu Furniture Co., Ltd.
12. Morewood Cabinetry Co., Ltd.
13. Qingdao Shousheng Industry Co., Ltd
14. Senke Manufacturing Company
15. Shandong Jinhua Wood Co., Ltd.
16. Shandong Longsen Woods Co., Ltd.

[19] *See APO and Service Procedures.*

[20] *See* 19 CFR 351.310(d).

[21] *See* 19 CFR 351.212(b)(1).

[22] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

17. Shanghai Zifeng International Trading Co., Ltd
18. Sheen Lead International Trading (Shanghai) Co., Ltd.
19. Shouguang Fushi Wood Co., Ltd.
20. Taishan Hongxiang Trading Co., Ltd.
21. Taishan Oversea Trading Co., Ltd.
22. Taizhou Overseas Int'l Ltd.
23. Weifang Yuanlin Woodware Co., Ltd.
24. Weihai Jarlin Cabinetry Manufacture Co., Ltd.
25. Xiamen Adler Cabinetry Co., Ltd.
26. Xiamen Golden Huanan Imp & Exp Co., Ltd.
27. Xuzhou Yihe Wood Co., Ltd.
28. Yixing Pengjia Technology Co., Ltd. (formally known as Yixing Pengjia Cabinetry Co., Ltd.)
29. Zhangzhou OCA Furniture Co., Ltd.
30. Zhongshan NU Furniture Co., Ltd.

Appendix IV

Companies Determined To Be Part of the China-Wide Entity

1. Deqing Meisheng Import and Export Co., Ltd.
2. Fujian Senyi Kitchen Cabinet Co., Ltd.
3. Fuzhou Hauster Kitchen Cabinet Manufacturing Co., Ltd.
4. Fuzhou Pyrashine Trading Co., Ltd.
5. Jiang Su Rongxin Import and Export Co., Ltd.
6. Jiangsu Sunwell Cabinetry Co., Ltd.
7. Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
8. Linshu Meibang Furniture Co., Ltd.
9. Linyi Bomei Furniture Co., Ltd
10. Nantong Aershin Cabinets Co., Ltd.
11. Qufu Xinyu Furniture Co., Ltd.
12. Shanghai Beautystar Cabinetry Co., Ltd.
13. Shanghai Zifeng Industries Development Co., Ltd.
14. Shenzhen Pengchengzhirong Trade Co., Ltd.
15. Xiamen Got Cheer Co., Ltd.
16. Yichun Dongmeng Wood Co., Ltd.
17. Yindu Kitchen Equipment Co., Ltd.
18. ZBOM Cabinets Co., Ltd.
19. Zaozhuang New Sharp Import & Export Trading Co., Ltd.
20. Zhongshan KM Cabinetry Co., Ltd.

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–896]

Common Alloy Aluminum Sheet From India: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department fo Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminary determines that countervailable subsidies are being provided to producers and exporters of common alloy aluminum sheet (aluminum sheet) from India. The period of review (POR) is January 1, 2022, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Samuel Evans, AD/CVD operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2420.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2021, Commerce published the countervailing duty (CVD) order on aluminum sheet from India.[1] On June 12, 2023, Commerce published in the **Federal Register** a notice of initiation of an administrative review of the *Order*.[2] On December 4, 2023, Commerce extended the deadline for the preliminary results until April 26, 2024.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included in an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https//access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https//access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The merchandise covered by this *Order* is aluminum sheet from India. For a complete description of the scope of the *Order,* see the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(3), Commerce's practice is to rescind an administrative review of a CVD order when it concludes that there are no suspended entries of subject merchandise during the POR.[5] Normally, upon completion of an administrative review, the suspended entries are liquidated at the countervailing duty assessment rate calculated for the review period.[6] Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the calculated countervailing duty assessment rate calculated for the review period.[7]

According to the CBP import data, Jindal Aluminum Limited (Jindal) did not have a reviewable entry of subject merchandise during the POR for which liquidatin is suspended.[8] Therefore, we notified interested parties that we intended to rescind this administrative review with respect to Jindal and provided parties an opportunity to submit comments, including factual information to demonstrate whether there were reviewable entries during the POR for Jindal.[9] We received no comments in response to this memorandum. Therefore, in the absence of suspended entries of subject merchandise duing the POR, in accordance with 19 CFR 351.213(d)(3), we are rescinding this administrative review with respect to Jindal.

Methodology

Commerce is conduing this CVD administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commercie preliminary determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[10] For a full description of the

[1] *See Common Alloy Aluminum Sheet from Bahrain, India, and the Republica of Turkey: Countervailing Duty Orders,* 86 FR 22144 (April 27, 2021) (Order).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38201 (June 12, 2023).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of 2022 Countervailing Duty Administrative Review,'' dated concurrently with, and hereby adopted by this notice (Preliminary Decision Memorandum).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination of the Countervailing Duty Investigation of Common Alloy Aluminum Sheet from India,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Admininstrative Review; 2015,* 82 FR 14349 (March 20, 2017); *see also Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[6] *See* 19 CFR 351.212(b)(2).

[7] *See* 19 CFR 351.213(d)(3).

[8] *See* Memorandum, ''Release of Customs and Broder Protection Data Query,'' dated June 23, 2023.

[9] *See* Memorandum, ''Notice of Intent to Rescind Review, In Part,'' dated December 27, 2023.

[10] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E)

methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Company Not Selected for Individual Examination

The Act and Commerce's regulations do not directly address the subsidy rate to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of that Act, which provides instructions for calculating the all-others rate in an investigation. Section 777A(e)(2) fo the Act provides that ''the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}.'' Section 705(c)(5)(A) of the Act states that for companies not investigated, in general we will determine an all-others rate by weight averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding *zero* and *de minimis* rates or any rate based on solely on the facts available.

According, to determine the rate for Virgo Aluminum Limited (Virgo), the company not selected for individual examination, Commerce's practice is to weight average the net subsidy rates for the selected mandatory respondents, excluding rates that are zero, *de minimis,* or based entirely on facts available.[11] We selected Hindalco Industries Limited (Hindalco) and Manaksia Aluminum Company Limited (MALCO) for review as mandatory respondents and preliminary determine that each received countervailable subsidies at above *de minimis* rates. Therefore, for the POR, we are assigning Virgo a weighted average of the subsidy rates calculated for Hindalco and MALCO using each company's public ranged data for the value of it's exports of subject merchandise to the United States.[12]

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rates for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate 2022 (percent *ad valorem*)
Hindalco Industries Limited[13]	54.12
Manaksia Aluminum Company Limited	2.90
Virgo Aluminum Limited	5.32

Disclousre and Public Comment

Commerce intends to disclose its calculations performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[14] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[15] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline. As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limted to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[16] Further we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administravtive review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing. An electronically filed hearing request must be received successfully in its enterety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by parties in their comments, within 120 days after the date of publication of these preliminary results.

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce will determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue intstruction to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expried (i.e., within 90 days of publication).

of the Act regarding benefit; and section 771(5)(A) of the Act regarding specifically.

[11] *See, e.g.,* Certain Pasta from Italy: Final Results of the 13th (2008) Countervailing Duty Administrative Review, 75 FR 37386, 37387 (June 29, 2010).

[12] *See* Memorandum, ''Calculation of Rate for Company Not Selected for Individual Examination,'' dated concurrently with this notice.

[13] As discussed in the Preliminary Decision Memorandum, Commerce has found the following compaies to be cross-owned with Hindalco; Hindalco-Almex Aerospace Limited, Minerals Minerals Limited, Utkal Alumina International Limited, Suvas Holding Limited, and Birla Copper Asoj Private Limited.

[14] See 19 CFR 351.309(d); see also Administrative Protective Order, Service, and Other Procedures in Antidumpting and Countervailing Duty Proceedings, 88 FR 67069, 67077 (Sepember 29, 2023).

[15] See 19 351.209(c)(2) and (d)(2).

[16] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[17] See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule, 88 FR 67069 (September 29, 2023).

For Jindal, the company for which we are rescinding this administrative review, Commerce will instruct CBP to assess countervailing duties on all apppropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue apprporate assessment instructions directly to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) fo the Act, Commerce also intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropirate. These cash deposit requirements, when imposed, shall remain in effect until futher notice.

Notificatin to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the Non-exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–09590 Filed 5–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–054]

Certain Aluminum Foil From the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Review, in Part; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that producers and exporters of certain aluminum foil (aluminum foil) from the People's Republic of China (China) received countervailable subsidies during the period of review, January 1, 2022, through December 31, 2022.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Natasia Harrison or Harrison Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1240 or (202) 482–7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2023, Commerce published a notice of initiation of an administrative review of the countervailing duty order on aluminum foil from China,[1] covering the requested companies.[2] As explained below, between July 20 and September 11, 2023, certain interested parties withdrew their review requests with respect to certain companies.[3] On July 24, 2023, Commerce selected Hangzhou Five Star Aluminium Co., Ltd. (Five Star) and Jiangsu Zhongji Lamination Materials Co., (HK) Limited (Zhongji HK) for individual examination as the mandatory respondents in this administrative review.[4] On November 30, 2023, Commerce extended the deadline for these preliminary results until April 26, 2024.[5]

For a complete description of the events that followed the initiation of this review, see the Preliminary Decision Memorandum.[6] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Scope of the Order

The product covered by the *Order* is aluminum foil from China. For a complete description of the scope of the *Order,* see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our conclusions, see the accompanying Preliminary Decision Memorandum.

Commerce notes that, in making these findings, it relied, in part, on facts available and, because it finds that the Government of China did not act to the

[1] *See Certain Aluminum Foil from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 83 FR 17360 (April 19, 2018); *see also Certain Aluminum Foil from the People's Republic of China: Notice of Court Decision Not in Harmony With the Amended Final Determination in the Countervailing Duty Investigation, and Notice of Amended Final Determination and Amended Countervailing Duty Order,* 85 FR 47730 (August 6, 2020) (collectively, *Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021, 38030 (June 12, 2023) (*Initiation Notice*).

[3] *See* Printpack, Inc.'s Letter, ''Withdrawal of Request for Administrative Review (Period of Review 1/1/2022–12/3112022),'' dated July 20, 2023; *see also* Novolex Bagcraft Inc.'s Letter, ''Withdrawal of Review Requests,'' dated July 27, 2023; and Sankyu-Thai Co., Ltd.'s Letter, ''Withdrawal of Request for Administrative Review,'' dated September 11, 2023 (collectively, Withdrawals of Review Requests).

[4] *See* Memorandum, ''Respondent Selection,'' dated July 24, 2023.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2022,'' dated November 30, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of Countervailing Duty Order on Certain Aluminum Foil from the People's Republic of China; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

best of its ability to respond to Commerce's requests for certain information, it drew an adverse inference, where appropriate, in selecting from among the facts otherwise available. For further information, see the Preliminary Decision Memorandum at the section titled ''Use of Facts Otherwise Available and Adverse Inferences.''

Rescission of Administrative Review, In Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraw the request within 90 days of the publication date of the notice of initiation of the requested review. As noted above certain interested parties timely withdrew their requests for review of specific companies.[8]

Because no other party requested a review of these 11 companies, and in accordance with 19 CFR 351.213(d)(1), we are rescinding the review with respect to these companies (*see* Appendix II).

Companies Not Selected for Individual Review

There are 20 companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available. In this review, the preliminary rates calculated for Five Star and Zhongji HK are above *de minimis* and not based entirely on facts available. Therefore, we are applying to the non-selected companies the average of the net subsidy rates calculated for Five Star and Zhongji HK, which we calculated using the publicly-ranged sales data submitted by Five Star and Zhongji HK.[9] This methodology to establish the rate for the non-selected companies uses section 705(c)(5)(A) of the Act, which governs the calculation of the ''all-others'' rate in an investigation, as guidance. For further information on the calculation of the non-selected respondent rate, refer to the section in the Preliminary Decision Memorandum entitled ''Non-Selected Companies Under Review.'' For a list of the non-selected companies, *see* Appendix III to this notice.

Preliminary Results of Review

Commerce preliminarily determines that the following countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
Hangzhou Five Star Aluminium Co., Ltd.[10]	30.66
Jiangsu Zhongji Lamination Materials Co., (HK) Limited[11]	19.23
Non-Selected Companies Under Review[12]	24.95

Assessment Rates

Consistent with section 751(a)(2)(C) of the Act, upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies for which this review is rescinded with these preliminary results, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue appropriate assessment instructions directly to CBP no later than 35 days after publication of this notice in the **Federal Register**.

Cash Deposit Requirements

Pursuant to section 751(a)(1) of the Act, upon issuance of the final results, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties for each of the companies listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, except where the

[8] *See* Withdrawals of Review Requests.

[9] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[10] As discussed in the Preliminary Decision Memorandum, Commerce finds the following companies to be to be cross-owned with Five Star: Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd. (Jiangsu Dingsheng); Dingsheng Aluminium Industries (Hong Kong) Trading Co.; Limited or Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd. (Dingsheng HK); Hangzhou Dingsheng Import & Export Co., Ltd. or Hangzhou Dingsheng Import and Export Co., Ltd. (Dingsheng IE); Hangzhou Teemful Aluminium Co., Ltd. (Teemful); Inner Mongolia Liansheng New Energy Material Joint-Stock Co., Ltd. (Liansheng); Inner Mongolia Xinxing New Material Co., Ltd. (Xinxing); Hangzou Dingsheng Industrial Group Co., Ltd. (Dingsheng Group); Hangzhou Dingcheng Aluminum Co., Ltd. (Dingcheng); Luoyang Longding Aluminium Co., Ltd. (Longding); and Walson (HK) Trading Co., Limited (Walson HK). Longding and Walson HK were listed separately in the *Initiation Notice.*

[11] As discussed in the Preliminary Decision Memorandum, Commerce finds finds the following companies to be to be cross-owned with Zhongji HK: Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji) (FKA Jiangsu Zhongji Lamination Materials Co., Ltd.); Jiangsu Huafeng Aluminium Industry Co., Ltd. (Jiangsu Huafeng); Shantou Wanshun New Material Group Co., Ltd. (Shantou Wanshun) (FKA Shantou Wanshun Package Material Stock Co., Ltd.); Anhui Zhongji Battery Foil Sci&Tech Co., Ltd. (Anhui Zhongji) (FKA Anhui Maximum Aluminium Industries Company Limited); and Sichuan Wanshun Zhongji Aluminium Industry Co., Ltd. (Sichuan Wanshun). Anhui Zhongji, Anhui Maximum Aluminium Industries Company Limited, Jiangsu Huafeng, Zhongji, and Shantou Wanshun Package Material Stock Co., Ltd. were listed separately in the *Initiation Notice. See* Preliminary Decision Memorandum at the ''Attribution'' section for further discussion regarding Zhongji, Shantou Wanshun and Anhui Zhongji's company name changes.

[12] *See* Appendix III for a list of the non-selected companies under review.

rate calculated in the final results is zero or *de minimis,* no cash deposit will be required. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of these preliminary results of review in the **Federal Register**.[13] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the deadline for filing case briefs.[14] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[15]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[16] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via ACCESS. An electronically-filed request must be received successfully, and in its entirety, by ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[18] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by the parties in any written briefs, no later than 120 days after the date of publication of these preliminary results.

Notification to Interested Parties

This administrative review and notice are in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

Companies Rescinded From the Review

1. Aluminum Corporation of China Limited
2. Dong-IL Aluminium Co., Ltd.
3. Dongwon Systems Corp.
4. Eastern Valley Co. Ltd.
5. Henan Mingtai Al. Industrial
6. Lotte Aluminium Co., Ltd.
7. SAM–A Aluminum Co., Ltd.
8. Sankyu-Thai Co., Ltd.
9. Shandong Nanshan Aluminium Co., Ltd.
10. Shanghai Sunho Aluminum Foil Co., Ltd.
11. Zhejiang Yongjie Aluminum Co., Ltd.

Appendix III

Non-Selected Companies Under Review

1. Alcha International Holdings Limited
2. Baotou Alcha Aluminum Co., Ltd.
3. Dingheng New Materials Co., Ltd.
4. Gränges Aluminum (Shanghai) Co., Ltd.
5. Guangxi Baise Xinghe Aluminum Industry Co., Ltd.
6. Hunan Suntown Marketing Limited
7. Jiangyin Dolphin Pack Ltd. Co.
8. Luoyang Longding Aluminium Industries Co., Ltd.
9. Shandong Yuanrui Metal Material Co., Ltd.
10. Shanghai Huafon Aluminium Corporation
11. Shanghai Shenhuo Aluminium Foil Co., Ltd.
12. Shanghai Shenyan Packaging Materials Co., Ltd.
13. SNTO International Trade Limited
14. Suntown Technology Group Corporation Limited
15. Thai Ding Li New Materials Co., Ltd.
16. Xiamen Xiashun Aluminium Foil Co., Ltd.
17. Yangtai Jintai International Trade Co., Ltd.
18. Yantai Donghai Aluminum Co., Ltd.
19. Yinbang Clad Material Co., Ltd.
20. Zhejiang Zhongjin Aluminum Industry Co., Ltd.

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[13] *See* 19 CFR 351.309(c)(1)(ii).

[14] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2).

[16] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[17] *See APO and Service Final Rule.*

[18] *See* 19 CFR 351.303.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Preliminary Determination of No Shipments and Rescission of Antidumping Duty Administrative Review, in Part; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is rescinding, in part, the administrative review of the antidumping duty (AD) order on tapered

toller bearings and parts thereof, finished and unfinished (TRBs) from the People's Republic of China (China) for the period of review (POR) June 1, 2022, through May 31, 2023. Further, Commerce preliminarily finds that Shanghai Tainai Bearing Co., Ltd. (Tainai) had no shipments during the POR.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Steven Seifert, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3350.

SUPPLEMENTARY INFORMATION:

Background

On February 26, 1990, Commerce published in the **Federal Register** the AD order on TRBs from China.[1] On June 1, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.[2] On June 30, 2023, Koyo Bearings North America LLC (Koyo, a domestic interested party) submitted a timely request that Commerce conduct an administrative review of the *Order* with respect to Tainai, C&U Group Shanghai Bearing Co., Ltd., Hangzhou C&U Automotive Bearing Co., Ltd., Hangzhou C&U Metallurgy Bearing Co., Ltd., Huangshi C&U Bearing Co., Ltd., and Sichuan C&U Bearing Co., Ltd.[3] Also on June 30, 2023, Tainai submitted a timely request that Commerce conduct an administrative review of the *Order* of its entries of subject merchandise during the POR.[4]

On August 3, 2023, Commerce published in the **Federal Register** a notice of initiation of administrative review with respect to entries of TRBs from China exported or produced by Tainai, C&U Group Shanghai Bearing Co., Ltd., Hangzhou C&U Automotive Bearing Co., Ltd., Hangzhou C&U Metallurgy Bearing Co., Ltd., Huangshi C&U Bearing Co., Ltd., and Sichuan C&U Bearing Co., Ltd., in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.221(c)(1)(i).[5]

On August 3, 2023, we placed on the record U.S. Customs and Border Protection (CBP) data for entries of TRBs from China during the POR, showing one suspended entry during the POR and invited interested parties to comment.[6] On August 10, 2023, JTEKT Bearings North America LLC. (JTEKT, a domestic interested party) submitted comments regarding the CBP data.[7] Tainai timely withdrew its request for a review of itself on August 10, 2023 [8] and on August 24, 2023, timely submitted a certification of no shipments.[9] On February 27, 2024, Commerce extended the preliminary results of this review until April 30, 2024.[10]

On April 4, 2024, Commerce notified all interested parties of its intent to rescind the instant review in full because there were no suspended entries of subject merchandise during the POR and invited interested parties to comment.[11] No interested party submitted comments to Commerce in response to this notice. Subsequently, on April 22, 2024, Commerce issued a memorandum [12] correcting an error in its Intent to Rescind Memorandum in which it incorrectly stated that it intended to rescind the review in full when it intended to rescind the review in part, with respect to five of the six companies listed in the *Initiation Notice.* No party submitted comments regarding the Correction to Intent to Rescind Memorandum.

Scope of the Order

Imports covered by the *Order* are shipments of tapered roller bearings and parts thereof, finished and unfinished, from China; flange, take up cartridge, and hanger units incorporating tapered roller bearings; and tapered roller housings (except pillow blocks) incorporating tapered rollers, with or without spindles, whether or not for automotive use. These products are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) item numbers 8482.20.00, 8482.91.00.50, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.700.6060, 8708.99.2300, 8708.99.27, 8708.99.4100, 8708.99.4850, 8708.99.6890, 8708.99.8115, and 8708.99.8180. Although the HTSUS item numbers are provided for convenience and customs purposes, the written description of the scope of the *Order* is dispositive.

Rescission of Review, In Part

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an AD order when there are no suspended entries of subject merchandise during the POR.[13] Normally, upon completion of an administrative review, the suspended entries are liquidated at the AD assessment rate calculated for the review period.[14] Therefore, for an administrative review to be conducted, there must be a suspended entry that Commerce can instruct CBP to liquidate at the AD assessment rate calculated for the review period.[15]

As noted above, there were no suspended entries of subject merchandise for five exporters subject to the review, C&U Group Shanghai Bearing Co., Ltd., Hangzhou C&U Automotive Bearing Co., Ltd., Hangzhou C&U Metallurgy Bearing Co., Ltd., Huangshi C&U Bearing Co., Ltd., and Sichuan C&U Bearing Co., Ltd. during the POR. Accordingly, in the absence of suspended entries of subject merchandise during the POR for these companies for which this review was initiated, we are hereby rescinding this administrative review, in part, with respect to these companies, in accordance with 19 CFR 351.213(d)(3).

[1] *See Tapered Roller Bearings from the People's Republic of China; Amendment to Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order in Accordance with Decision Upon Remand,* 55 FR 6669 (February 26, 1990) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 35837 (June 1, 2023).

[3] *See* Petitioner's Letter, ''Koyo Bearings North America LLC's Request for Administrative Review,'' dated June 30, 2023.

[4] *See* Tainai's Letter, ''Request for Review,'' dated June 30, 2023. On June 30, 2023, Changshan Peer Bearing Co., Ltd. (CPZ, a Chinese producer and exporter), requested a review of itself and subsequently, timely withdrew its request prior to the publication of the *Initiation Notice,* such that we did not include CPZ in the *Initiation Notice.*

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023).

[6] *See* Memorandum, ''Release of U.S. Customs and Border Protection Entry Data,'' dated August 3, 2023.

[7] *See* JKEKT's Letter, ''JTEKT Bearings North America LLC's Comments on CBP Data Release,'' dated August 10, 2023. JKEKT noted that ''Koyo Bearings North America LLC officially changed its legal name to JTEKT Bearings North America LLC on April 1, 2023. The entry of appearance and APO application filed on behalf of our firm has been amended to reflect this change.''

[8] *See* Tainai's Letter, ''Withdraw Request for Review,'' dated August 10, 2023.

[9] *See* Tainai's Letter, ''No Shipment Certification,'' dated August 24, 2023.

[10] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 27, 2024.

[11] *See* Memorandum, ''Notice of Intent to Rescind Review,'' dated April 4, 2024 (Intent to Rescind Memorandum).

[12] *See* Memorandum, ''Correction on Companies to Rescind Regarding Intent to Rescind Memorandum,'' dated April 22, 2024 (Correction to Intent to Rescind Memorandum).

[13] *See, e.g., Dioctyl Terephthalate from the Republic of Korea: Rescission of Antidumping Administrative Review; 2021–2022,* 88 FR 24758 (April 24, 2023); *see also Certain Carbon and Alloy Steel Cut-to-Length Plate from the Federal Republic of Germany: Recission of Antidumping Administrative Review; 2020–2021,* 88 FR 4157 (January 24, 2023).

[14] *See* 19 CFR 351.212(b)(1).

[15] *See* 19 CFR 351.213(d)(3).

Preliminary Determination of No Shipments

Tanai, an exporter that received a separate rate in a previous segment of the proceeding and is subject to this review, reported that it had no shipments of subject merchandise during the POR. We requested that CBP report any contrary information. CBP reported that an entry was made under the CBP 10-digit case number for Tainai, *i.e.,* the importer of record entered the shipment pursuant to Tainai's cash deposit requirement, but the information for the suspended entry identifies a different manufacturer and exporter for that merchandise.[16] Therefore, based on our analysis of information from CBP and the certification provided by Tainai, we preliminarily determine that Tanai made no shipments of subject merchandise to the United States during the POR. Further, consistent with Commerce's practice, we find that it is not appropriate to rescind the review with respect to Tanai, but rather to complete the review and issue appropriate assessment instructions to CBP based on the final results of review.[17]

Assessment

For the companies for which this review is being rescinded, in part, Commerce will instruct CBP to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). With respect to the recission of this review, in part, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register.**

When Commerce determines that an exporter under review made no shipments of subject merchandise during the POR, upon issuing the final results, Commerce will instruct CBP to liquidate any suspended entries of subject merchandise that entered under that exporter's cash deposit requirement, *i.e.,* under the exporter's CBP case number, during the POR at the weighted-average dumping margin for the China-wide entity.[18]

With respect to Tainai, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register.** If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Rates

As a result of this administrative review, Commerce does not intend to revise the cash deposit requirements for estimated antidumping duties for entries subject to the *Order.*

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4) and 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–09588 Filed 5–1–24; 8:45 am]

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[16] *See* Memorandum, ''No Shipment Inquiry for Shanghai Tainai Bearings Co., Ltd. (A–570–601) during the period 06/01/2022 through 05/31/2023,'' dated October 18, 2023.

[17] *See, e.g., Certain Steel Threaded Rod from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments;* 2018–2019, 84 FR 71900 (December 30, 2019).

[18] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–825]

Phosphate Fertilizers from the Russian Federation: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from the Russian Federation (Russia). The period of review (POR) is January 1, 2022, through December 31, 2022.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Shane Subler or William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6241 and (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2023, Commerce published a notice of initiation of an administrative review of the countervailing duty (CVD) order on phosphate fertilizers from Russia.[1] On November 27, 2023, Commerce extended the deadline for the preliminary results of this review until April 26, 2024.[2]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023) (*Initiation Notice*).

[2] *See* Memorandum, ''Extension of Deadline for the Preliminary Results of the 2022 Countervailing Duty Administrative Review,'' dated November 27, 2023.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2022: Phosphate Fertilizers from the Russian Federation,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx/.*

Scope of the Order

The merchandise covered by the order is phosphate fertilizers. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested the review withdraw their review requests within 90 days of the date of publication of the notice of initiation for the requested review.[4] On September 11, 2023, The Mosaic Company (the petitioner) withdrew its request for the review of Industrial Group Phosphorite LLC, a member of the EuroChem Group, within the 90-day deadline.[5] No other parties requested an administrative review of this company. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding the administrative review of Industrial Group Phosphorite LLC. For additional information regarding this determination, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rate for the period January 1, 2022, through December 31, 2022:

Producer/exporter	Subsidy rate (percent *ad valorem*)
Joint Stock Company Apatit[7]	18.83

Disclosure and Public Comment

Commerce intends to disclose its calculations performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance.[8] A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Interested parties that submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[11] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Unless the deadline is extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Verification

As provided in section 782(i)(3) of the Act, Commerce intends to verify the information relied upon for its final results.

Assessment Rate

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned a subsidy rate in the amount shown above for the producer/exporter shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review.

[4] *See Initiation Notice,* 88 FR 38021.

[5] *See* Petitioner's Letter, ''Withdrawal of Request for Countervailing Duty Administrative Review,'' dated September 11, 2023.

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds the following companies to be cross-owned with JSC Apatit: PhosAgro Public Joint Stock Company; Limited Liability Company PhosAgro-Region; Limited Liability Company PhosAgro-Belgorod; Limited Liability Company PhosAgro-Don; Limited Liability Company PhosAgro-Kuban; Limited Liability Company PhosAgro-Lipetsk; Limited Liability Company PhosAgro-Kursk; Limited Liability Company PhosAgro-Orel; Limited Liability Company PhosAgro-Stavropol; Limited Liability Company PhosAgro-Volga; Limited Liability Company PhosAgro-SeveroZapad; Limited Liability Company PhosAgro-Tambov; and Limited Liability Company PhosAgro-Sibir.

[8] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 for general filing requirements.

[9] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[12] *See APO and Service Procedures.*

For the company for which this review is rescinded, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

For the company remaining in the review, we intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for the company (and its cross-owned affiliates) listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results and partial rescission of review are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, 19 CFR 351.213(d)(1), and 19 CFR 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–09585 Filed 5–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) received scope ruling applications, requesting that scope inquiries be conducted to determine whether identified products are covered by the scope of antidumping duty (AD) and/or countervailing duty (CVD) orders and that Commerce issue scope rulings pursuant to those inquiries. In accordance with Commerce's regulations, we are notifying the public of the filing of the scope ruling applications listed below in the month of March 2024.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Terri Monroe, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–1384.

Notice of Scope Ruling Applications

In accordance with 19 CFR 351.225(d)(3), we are notifying the public of the following scope ruling applications related to AD and CVD orders and findings filed in or around the month of March 2024. This notification includes, for each scope application: (1) identification of the AD and/or CVD orders at issue (19 CFR 351.225(c)(1)); (2) concise public descriptions of the products at issue, including the physical characteristics (including chemical, dimensional and technical characteristics) of the products (19 CFR 351.225(c)(2)(ii)); (3) the countries where the products are produced and the countries from where the products are exported (19 CFR 351.225(c)(2)(i)(B)); (4) the full names of the applicants; and (5) the dates that the scope applications were filed with Commerce and the name of the ACCESS scope segment where the scope applications can be found.[1] This notice does not include applications which have been rejected and not properly resubmitted. The scope ruling applications listed below are available on Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), at *https://access.trade.gov.*

Scope Ruling Applications

Passenger Vehicle and Light Truck Tires from Taiwan (A–583–869); temporary-use spare tires;[2] produced in and exported from Taiwan; submitted by Cheng Shin Rubber USA Inc.; March 11, 2024; ACCESS scope segment ''SCO—T-Type.''

Aluminum Extrusions from the People's Republic of China (China) (A–570–967/C–570–968); aluminum extrusion parts of vacuum cleaner and mopping systems;[3] produced in and exported from China; submitted by Kaivac, Inc.; March 13, 2024; ACCESS scope segment ''SCO—Kaivac Mop & Vacuum Products.''

Certain Steel Wheels 12 to 16.5 Inches in Diameter from China (A–570–090/C–570–091); certain passenger vehicle and light truck wheels;[4] produced in and exported from China; submitted by Allied Wheel Components, Inc.; March

[1] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300, 52316 (September 20, 2021) (*Final Rule*) (''It is our expectation that the **Federal Register** list will include, where appropriate, for each scope application the following data: (1) identification of the AD and/or CVD orders at issue; (2) a concise public summary of the product's description, including the physical characteristics (including chemical, dimensional and technical characteristics) of the product; (3) the country(ies) where the product is produced and the country from where the product is exported; (4) the full name of the applicant; and (5) the date that the scope application was filed with Commerce.'')

[2] The products are temporary-use spare tires with a ''T'' prefix on the sidewall markings. The numerical size designation is 155/60R18.

[3] The products are aluminum extrusion parts made of 6063 aluminum, including vacuum and mop handles, mop heads, and mop trowels, that are imported as mop and vacuum parts assemblies. The application includes products that are imported as accessories to the mopping and vacuum systems and are individually packaged for sale. The application also includes products that are imported to be incorporated into a finished unit, with a small percentage being sold as spare parts.

[4] The products are certain steel wheels with dimensions (15 x 5; 15 x 6; 15 x 7; and 16 x 7 inches) that fall within the dimensions of the scope language but are physically unsuitable for use on road or highway trailers or other towable equipment. The steel wheels are identical in dimension and purpose as products previously found to be out of scope for another importer based on key physical characteristics of rim size, bolt patterns, offset and load capacity.

26, 2024; ACCESS scope segment ''SCO—Allied Wheel III.''

Notification to Interested Parties

This list of scope ruling applications is not an identification of scope inquiries that have been initiated. In accordance with 19 CFR 351.225(d)(1), if Commerce has not rejected a scope ruling application nor initiated the scope inquiry within 30 days after the filing of the application, the application will be deemed accepted and a scope inquiry will be deemed initiated the following day—day 31.[5] Commerce's practice generally dictates that where a deadline falls on a weekend, Federal holiday, or other non-business day, the appropriate deadline is the next business day.[6] Accordingly, if the 30th day after the filing of the application falls on a non-business day, the next business day will be considered the ''updated'' 30th day, and if the application is not rejected or a scope inquiry initiated by or on that particular business day, the application will be deemed accepted and a scope inquiry will be deemed initiated on the next business day which follows the ''updated'' 30th day.[7]

In accordance with 19 CFR 351.225(m)(2), if there are companion AD and CVD orders covering the same merchandise from the same country of origin, the scope inquiry will be conducted on the record of the AD proceeding. Further, please note that pursuant to 19 CFR 351.225(m)(1), Commerce may either apply a scope ruling to all products from the same country with the same relevant physical characteristics, (including chemical, dimensional, and technical characteristics) as the product at issue, on a country-wide basis, regardless of the producer, exporter, or importer of those products, or on a company-specific basis.

For further information on procedures for filing information with Commerce through ACCESS and participating in scope inquiries, please refer to the Filing Instructions section of the Scope Ruling Application Guide, at *https://access.trade.gov/help/Scope_Ruling_Guidance.pdf.* Interested parties, apart from the scope ruling applicant, who wish to participate in a scope inquiry and be added to the public service list for that segment of the proceeding must file an entry of appearance in accordance with 19 CFR 351.103(d)(1) and 19 CFR 351.225(n)(4). Interested parties are advised to refer to the case segment in ACCESS as well as 19 CFR 351.225(f) for further information on the scope inquiry procedures, including the timelines for the submission of comments.

Please note that this notice of scope ruling applications filed in AD and CVD proceedings may be published before any potential initiation, or after the initiation, of a given scope inquiry based on a scope ruling application identified in this notice. Therefore, please refer to the case segment on ACCESS to determine whether a scope ruling application has been accepted or rejected and whether a scope inquiry has been initiated.

Interested parties who wish to be served scope ruling applications for a particular AD or CVD order may file a request to be included on the annual inquiry service list during the anniversary month of the publication of the AD or CVD order in accordance with 19 CFR 351.225(n) and Commerce's procedures.[8]

Interested parties are invited to comment on the completeness of this monthly list of scope ruling applications received by Commerce. Any comments should be submitted to James Maeder, Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to *CommerceCLU@trade.gov.*

This notice of scope ruling applications filed in AD and CVD proceedings is published in accordance with 19 CFR 351.225(d)(3).

Dated: April 26, 2024.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2024–09518 Filed 5–1–24; 8:45 am]

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[5] In accordance with 19 CFR 351.225(d)(2), within 30 days after the filing of a scope ruling application, if Commerce determines that it intends to address the scope issue raised in the application in another segment of the proceeding (such as a circumvention inquiry under 19 CFR 351.226 or a covered merchandise inquiry under 19 CFR 351.227), it will notify the applicant that it will not initiate a scope inquiry, but will instead determine if the product is covered by the scope at issue in that alternative segment.

[6] *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

[7] This structure maintains the intent of the applicable regulation, 19 CFR 351.225(d)(1), to allow day 30 and day 31 to be separate business days.

[8] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that certain activated carbon (activated carbon) from the People's Republic of China (China) was sold in the United States at prices below normal value (NV) during the period of review (POR), April 1, 2022, through March 31, 2023. We invite interested parties to comment on these preliminary results of review.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Andrew Hart or Katie Smith, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1058 or (202) 482–0557, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2007, Commerce published in the **Federal Register** the antidumping duty (AD) order on activated carbon from China.[1] On April 4, 2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order,* covering the POR, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act).[2] On June 12, 2023, based on timely requests for review from certain interested parties,[3]

[1] *See Notice of Antidumping and Countervailing Duty Order: Certain Activated Carbon from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 72 FR 20988 (April 27, 2007) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 199616 (April 4, 2023).

[3] *See* Carbon Activated Tianjin Co., Ltd. (CA Tianjin)'s Letter, ''Request for Antidumping Administrative Review,'' dated April 26, 2023; *see also,* Ningxia Huahui Environmental Technology Co., Ltd. (Huahui)'s Letter, ''Request for Administrative Review,'' dated April 27, 2023; Ningxia Mineral & Chemical Limited (Ningxia Minerals)'s Letter, ''Request for Administrative Review,'' dated April 27, 2023; Tancarb Activated Carbon Co., Ltd.'s Letter (Tancarb), ''Request for Administrative Review,'' dated April 27, 2023;

Continued

Commerce initiated an administrative review of the *Order* covering the POR.[4] The administrative review covers 20 companies including the two mandatory respondents, Jilin Bright Future Chemicals Co., Ltd. (Jilin Bright) and Ningxia Guanghua Cherishment Activated Carbon Co., Ltd. (GHC). On December 6, 2023, Commerce extended the deadline for the preliminary results of this review until April 26, 2024.[5]

Scope of the Order

The product covered by the *Order* is activated carbon from China. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.[6]

Separate Rates

Commerce preliminarily determines that Jilin Bright and GHC, the companies individually examined in this review, and the 12 companies, not individually examined and listed in Appendix II to this notice, are eligible to receive separate rates in this administrative review.[7]

The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate rate respondents which Commerce did not examine individually in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins calculated for individually-examined respondents, excluding dumping margins that are zero, *de minimis,* or based entirely on facts available.

For the preliminary results of this review, Commerce determined the estimated dumping margins for Jilin Bright and GHC are $2.01/kg and $1.17/kg respectively. For the reasons explained in the Preliminary Decision Memorandum, we are assigning to the 12 non-examined respondents which qualify for a separate rate in this review, an estimated dumping margin of $1.43/kg, consistent with Commerce's practice and section 735(c)(5)(A) of the Act.

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[8] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* $2.42/kilogram) is not subject to change.[9] For the reasons explained in the Preliminary Decision Memorandum, Commerce considers certain companies for which a review was requested and which did not demonstrate separate rate eligibility, listed in Appendix II to this notice, to be part of the China-wide entity.[10]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. We calculated export price in accordance with section 772 of the Act. Because China is a non-market economy country within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum.[11] A list of topics discussed in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

For companies that established their eligibility for a separate rate,[12] Commerce preliminarily determines that the following estimated weighted-average dumping margins exist for the period April 1, 2022, through March 31, 2023: [13]

Exporter	Weighted-average dumping margin (U.S. dollars per kilogram) [14]
Jilin Bright Future Chemicals Co., Ltd.	2.01
Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd.	1.17
Review-Specific Rate Applicable For Non-Selected Companies Under Review [15]	1.43

Calgon Carbon Corporation and Norit Americas Inc. (the petitioners)'s Letter, ''Petitioners' Request for Initiation of 16th Annual Administrative Review,'' dated April 28, 2023; Shanxi Sincere Industrial Co., Ltd. (Shanxi Sincere)'s and Tianjin Channel Filters Co., Ltd. (Tianjin Channel Filters)'s Letter, ''Request for Administrative Review,'' dated April 28, 2023; Jacobi Carbons Tianjin International Trade Co., Ltd., and Jacobi Absorbent Materials Co., Ltd. (collectively, Jacobi Carbons AB and Affiliates)' Letter, ''Jacobi's Request for Administrative Review,'' dated April 28, 2023 (We also received a review request for Jacobi Carbons, Inc.; however, Jacobi Carbons, Inc. is a U.S. affiliate of Jacobi Carbons AB as such, this company was not included in the *Initiation Notice*); Datong Hongdi Carbon Co., Ltd. (Datong Hongdi)'s Letter, ''AD Request for Review,'' dated April 28, 2023; Bengbu Modern Environmental Co., Ltd. (Bengbu)'s Letter, '' AD Request for Review,'' dated April 28, 2023; Jilin Bright Future Chemicals Co., Ltd. (Jilin Bright)'s Letter, ''Request for Administrative Review,'' dated May 1, 2023; Datong Juqiang Activated Carbon Co., Ltd. (Datong Juqiang)'s, Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd. (GHC)'s, Datong Municipal Yunguang Activated Carbon Co., Ltd. (Datong Municipal)'s, and Shanxi Industry Technology Trading Co., Ltd. (Shanxi Industry)'s Letter, ''Request for Antidumping Administrative Review,'' dated May 1, 2023; and Petitioners' Letter, ''Supplement to Petitioners' Request for Initiation of 16th Annual Administrative Review,'' dated May 1, 2023.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023) (*Initiation Notice*).

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated December 6, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2022–2023 Administrative Review of the Antidumping Duty Order on Certain Activated Carbon from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* Appendix II; *see also* Preliminary Decision Memorandum at ''Separate Rate Recipients'' section.

[8] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[9] *See Order.*

[10] *See* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

[11] *See* Preliminary Decision Memorandum at ''Discussion of the Methodology'' section.

[12] *See* Preliminary Decision Memorandum

[13] *See* Appendix II for the list of companies under review receiving a separate rate.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to interested parties within five days after public announcement, or if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**.[16]

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[17] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[18] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[19]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[20] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[21]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.[22] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[23] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline.

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review. Upon completion of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[24]

If the individually examined respondents' weighted-average dumping margins are above *de minimis* (*i.e.,* 0.50 percent) in the final results of this review, we will calculate importer-specific per-unit assessment rates for each respondent by dividing the total amount of dumping calculated for examined sales to the importer or customer by the total sales quantity associated with those transactions. Where an importer-specific or customer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries that were not reported in the U.S. sales database submitted by each mandatory respondent individually examined during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate.[25]

For the respondents that were not selected for individual examination in this administrative review but qualified for a separate rate, the per unit assessment rate will be the rate established for these companies in the final results of review.

For the final results of this review, if we continue to treat the six companies identified in Appendix II to this notice as part of the China-wide entity, we will instruct CBP to apply the China-wide per-unit assessment rate to all entries of subject merchandise during the POR which were exported by those companies.

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) for the subject merchandise exported by the companies listed above that have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will

[14] In the second administrative review of the *Order,* Commerce determined that it would calculate per-unit weighted-average dumping margins and assessment amounts for all future reviews. *See Certain Activated Carbon from the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 75 FR 70208, 70211 (November 17, 2010).

[15] *See* Appendix II.

[16] *See* 19 CFR 351.224(b).

[17] *See* 19 CFR 351.303 (for general filing requirements).

[18] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[19] *See* 19 CFR 351.309(c)(2) and (d)(2).

[20] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[21] *See APO and Service Final Rule,* 88 FR at 67077.

[22] *See* 19 CFR 351.310(d).

[23] *See* 19 CFR 351.303.

[24] *See* 19 CFR 351.212(b)(1).

[25] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of Methodology
V. Currency Conversion
VI. Recommendation

Appendix II

Review-Specific Rate Applicable for Non-Selected Companies Under Review

1. Bengbu Modern Environmental Co., Ltd.
2. Carbon Activated Tianjin Co., Ltd.
3. Datong Hongdi Carbon Co., Ltd.
4. Datong Juqiang Activated Carbon Co., Ltd.
5. Datong Municipal Yunguang Activated Carbon Co., Ltd.
6. Jacobi Carbons AB; Jacobi Carbons Industry (Tianjin) Co., Ltd.; Tianjin Jacobi International Trading Co. Ltd.; Jacobi Adsorbent Materials
7. Ningxia Huahui Environmental Technology Co., Ltd.
8. Ningxia Mineral & Chemical Limited
9. Shanxi Industry Technology Trading Co., Ltd.
10. Shanxi Sincere Industrial Co., Ltd.
11. Tancarb Activated Carbon Co., Ltd.
12. Tianjin Channel Filters Co., Ltd.

Companies Considered To Be Part of the China-Wide Entity

1. Beijing Pacific Activated Carbon Products Co., Ltd.
2. Shanxi Dapu International Trade Co., Ltd.
3. Shanxi DMD Corp.
4. Shanxi Tianxi Purification Filter Co., Ltd.
5. Sinoacarbon International Trading Co., Ltd.
6. Tianjin Maijin Industries Co., Ltd.

[FR Doc. 2024–09582 Filed 5–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–714–001]

Phosphate Fertilizers From the Kingdom of Morocco: Preliminary Results of the Countervailing Duty Administrative Review, 2022

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of phosphate fertilizers from the Kingdom of Morocco (Morocco). The period of review (POR) is January 1, 2022, through December 31, 2022.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or Jaron Moore, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482–3640, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 28, 2023, we received a request from The Mosaic Company (the petitioner) to conduct an administrative review with respect to OCP S.A. (OCP).[1] On June 12, 2023, Commerce published a notice of initiation of an administrative review of the countervailing duty (CVD) order on phosphate fertilizers from Morocco.[2] On December 12, 2023, Commerce extended the deadline for the preliminary results of this review until April 26, 2024.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included at the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx/*.

Scope of the Order

The merchandise covered by the order is phosphate fertilizers. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution from an authority that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rate for the period January 1, 2022, through December 31, 2022:

Producer/exporter	Subsidy rate (percent *ad valorem*)
OCP S.A.[6]	14.21

Disclosure and Public Comment

Commerce intends to disclose its calculations performed to interested

[1] *See* Petitioner's Letter, ''Request for Countervailing Duty Administrative Review,'' dated April 28, 2023.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023) (*Initiation Notice*).

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results of the 2020–2021 Countervailing Duty Administrative Review,'' dated December 12, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review of Phosphate Fertilizers from the Kingdom of Morocco; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] As discussed in the Preliminary Decision Memorandum, Commerce preliminarily finds the following companies to be cross-owned with OCP S.A.: Nutircrops S.A.; Jorf Fertilizers Company I; Jorf Fertilizers Company II; Jorf Fertilizers Company III; Jorf Fertilizers Company IV; and Jorf Fertilizers Company V.

parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance.[7] A timeline for the submission of case briefs and written comments will be notified to interested parties at a later date. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[8] Interested parties that submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[9]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[10] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Unless the deadline is extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rate

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned the subsidy rate in the amount shown above for OCP. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review.

We will instruct CBP to assess countervailing duties on all appropriate entries at the subsidy rate calculated in the final results of this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for OCP (and its cross-owned affiliates) on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. The cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–09586 Filed 5–1–24; 8:45 am]

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[7] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 for general filing requirements.

[8] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See APO and Service Procedures.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–053]

Certain Aluminum Foil From People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Duty Administrative Review, and Preliminary Determination of No Shipments; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain producers and/or exporters made sales of certain aluminum foil (aluminum foil) at less than normal value during the period of review (POR), April 1, 2022, through March 31, 2023. Additionally, Commerce is rescinding this administrative review with respect to certain companies. Interested parties are invited to comment on these preliminary results of this review.

DATES: Applicable May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4475.

SUPPLEMENTARY INFORMATION:

Background

On June 12, 2023, in response to review requests from multiple parties, Commerce published the notice of initiation of an administrative review of the antidumping duty order on certain aluminum foil from the People's Republic of China (China),[1] covering 45 companies.[2] Between July 31 and September 11, 2023, all requests for review were timely withdrawn for certain companies.[3] On December 8, 2023, we extended the deadline for these preliminary results of review until April 26, 2024.[4]

For a summary of the events that occurred since the initiation of this review and the analysis for these preliminary results, *see* the Preliminary Decision Memorandum.[5] The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice.

Scope of the Order

The merchandise covered by the *Order* is certain aluminum foil from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). In determining the dumping margins in this review, we calculated export prices in accordance with section 772 of the Act. Because Commerce has determined that China is a non-market economy country [6] within the meaning of section 771(18) of the Act, Commerce calculated normal value in accordance with section 773(c) of the Act. For a full description of the methodology underlying the preliminary results of this review, *see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if all parties that requested a review withdraw their requests within 90 days of the publication date of the notice of initiation of the requested review. As noted above, the following companies timely withdrew their review requests and no other party requested an administrative review of these companies: Galex Inc.; Lotte Aluminium Co., Ltd.; Sama Aluminium Co Ltd.; Korea Aluminium Co., LTD.; Kataman Metals; Prosvic Sales Inc.; Sankyu-Thai Co., Ltd.; and Suzhou Xin Zhao Jin Aluminum Foil Co., Ltd. Therefore, we are rescinding this review with respect to these eight companies, in accordance with 19 CFR 351.213(d)(1).

Preliminary Determination of No Shipments

Based on the no-shipment certifications, our analysis of the results of the CBP data queries, and the fact that CBP identified no information that contradicted certain no-shipment claims, we preliminarily determine that Anhui Zhongji Battery Foil Science & Technology Co., Ltd. (Anhui Zhongji), Anhui Maximum Aluminum Industries Company Ltd. (Anhui Maximum), Manakin Industries, LLC (Manakin), and Xiamen Xiashun Aluminium Foil Co., Ltd. (Xiashun) did not have any shipments of subject merchandise to the United States during the POR. Consistent with Commerce's practice in non-market economy cases, we have not rescinded the review with respect to Anhui Zhongji, Anhui Maximum, Manakin, and Xiashun, but we will continue the review of these companies and issue instructions to CBP based on the final results of the review.[7]

Preliminary Affiliation and Single Entity Determination

Consistent with Commerce's treatment of Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited; Hangzhou Dingsheng Import & Export Co., Ltd.; Hangzhou Five Star Aluminium Co., Ltd.; Hangzhou Teemful Aluminium Co., Ltd.; Inner Mongolia Liansheng New Energy Material Co.; and Inner Mongolia Xinxing New Energy Material Co., Ltd. (collectively, Dingsheng) in a prior segment of this proceeding,[8] we have continued to find that these companies are affiliated entities, pursuant to sections 771(33)(E), (F), and (G) of the Act, and that they should be treated as a single entity pursuant to 19 CFR 351.401 (f)(1)–(2). Consistent with Commerce's treatment of Jiangsu Zhongji Lamination Materials Co., Ltd., Jiangsu Zhongji Lamination Materials Stock Co., Ltd., Jiangsu Huafeng Aluminium Industry Co., Ltd., and Jiangsu Zhongji Lamination Materials Co., (HK) Limited, (collectively, Zhongji) in a prior segment of this proceeding,[9] we have continued to find

[1] *See Certain Aluminum Foil from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 83 FR 17362 (April 19, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023) which includes a previously omitted company, ''Manakin Industries, LLC,'' as a respondent in this administrative review.

[3] *See* Suzhou Xin Zhao Jin Aluminum Foil Co., Ltd.'s Letter, ''Request to Withdraw from Administrative Review,'' dated July 31, 2023; *see also* Glenroy Inc's Letter, ''Request to Withdraw from Administrative Review,'' dated July 31, 2023; Tekni-Plex, Inc. and Tri-Seal Opco, LLC (Tekni-Plex's) Letter, ''Partial Withdrawal of Administrative Review Request,'' dated August 16, 2023; Paxxus, Inc.'s Letter, ''Partial Withdrawal of Administrative Review Request,'' dated August 21, 2023; Sankyu-Thai Co., Ltd.'s Letter, ''Withdrawal of Request for Administrative Review,'' dated September 11, 2023; and Fres-co System USA, Inc.'s Letter, ''Partial Withdrawal of Administrative Review Request,'' dated September 11, 2023.

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated December 8, 2023.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2022–2023 Administrative Review of the Antidumping Duty Order on Certain Aluminum Foil from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination,* 82 FR 50858, 50861 (November 2, 2017) (*Foil from China Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM) (citing Memorandum, ''China's Status as a Non-Market Economy,'' dated October 26, 2017), unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 83 FR 9282 (March 5, 2018) (*Foil from China Final Determination*).

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (*NME Practice*); *see also* Appendix II.

[8] *See Foil from China Preliminary Determination* PDM at 16–18, unchanged in *Foil from China Final Determination.* We find that record evidence supports continuing to treat these companies as a collapsed entity in this review. *See* Memorandum, ''Dingsheng Analysis for the Preliminary Results,'' dated concurrently with this notice.

[9] In the less-than-fair-value investigation, we collapsed the following companies as a single entity: Jiangsu Zhongji Lamination Materials Co., (HK) Ltd.; Jiangsu Zhongji Lamination Materials

that these companies are affiliated entities, pursuant to sections 771(33)(E), (F), and (G) of the Act, and that they should be treated as a single entity pursuant to 19 CFR 351.401 (f)(1)–(2). For additional information, *see* the Preliminary Decision Memorandum.

Separate Rates

Commerce preliminarily determines that Dingsheng and Zhongji, the two companies individually examined in this review, demonstrated their eligibility for a separate rate.[10] We also preliminarily determine that Dong-IL Aluminium Co., Ltd. (Dong-IL), Dongwon Systems Corp. (Dongwon), Eastern Valley Co., Ltd. (Eastern Valley), Granges Aluminum (Shanghai) Co., Ltd. (Granges Aluminum), Shanghai Shenyan Packaging Materials Co., Ltd. (Shanghai Shenyan), and Suzhou Manakin Aluminum Processing Technology Co., Ltd. (Suzhou Manakin Aluminum), Suzhou Manakin Trading Co., Ltd. (Suzhou Manakin Trading), companies not individually examined in this review, demonstrated their eligibility for a separate rate.[11]

The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review. Section 735(c)(5)(A) of the Act states that the all-others rate should be calculated by averaging the weighted-average dumping margins calculated for individually examined respondents, excluding dumping margins that are zero, *de minimis,* or based entirely on facts available.

For the preliminary results of this review, Commerce determined estimated dumping margins for Dingsheng and Zhongji to be 59.52, and 75.53 percent, respectively. For the reasons explained in the Preliminary Decision Memorandum, we are assigning the 67.53 percent rate to the seven non-examined respondents, Dong-IL, Dongwon, Eastern Valley, Granges Shanghai, Shanghai Shenyan, Suzhou Manakin Aluminum, and Suzhou Manakin Trading which qualify for a separate rate in this review, consistent with Commerce's practice and section 735(c)(5)(A) of the Act.[12]

China-Wide Entity

In accordance with Commerce's policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the China-wide entity.[13] Because no party requested a review of the China-wide entity, the China-wide entity is not under review, and the weighted-average dumping margin for the China-wide entity (*i.e.,* 105.80 percent) [14] is not subject to change. *See* the Preliminary Decision Memorandum for further discussion.

Aside from the companies for which we preliminarily find no shipments and the company for which the review is being rescinded, Commerce considers the 16 companies for which a review was requested and did not demonstrate separate rate eligibility to be part of the China-wide entity. Consequently, we have assigned these 16 companies to the China-wide entity and they will be subject to the China-wide entity rate.[15] For a listing of these companies, *see* Appendix II of this notice.

Preliminary Results of Review

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist for the period April 1, 2022, through March 31, 2023:

Exporter	Weighted-average dumping margin (percent)
Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited (Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd.)/Hangzhou Dingsheng Import & Export Co., Ltd. (Hangzhou Dingsheng Import and Export Co., Ltd.)/Hangzhou Five Star Aluminium Co., Ltd./Hangzhou Teemful Aluminium Co., Ltd./Inner Mongolia Liansheng New Energy Material Co./Inner Mongolia Xinxing New Energy Material Co., Ltd	59.52
Jiangsu Zhongji Lamination Materials Co., (HK) Limited/Jiangsu Zhongji Lamination Materials Stock Co., Ltd./Jiangsu Huafeng Aluminium Industry Co., Ltd./Jiangsu Zhongji Lamination Materials Co., Ltd	75.53
Dong-IL Aluminium Co., Ltd	67.53
Dongwon Systems Corp	67.53
Eastern Valley Co., Ltd	67.53
Granges Aluminum (Shanghai) Co., Ltd	67.53
Shanghai Shenyan Packaging Materials Co., Ltd	67.53
Suzhou Manakin Aluminum Processing Technology Co., Ltd	67.53
Suzhou Manakin Trading Co., Ltd	67.53

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Stock Co., Ltd.; Jiangsu Zhongji Lamination Materials Co., Ltd.; and Jiangsu Huafeng Aluminum Industry Co., Ltd. *See Foil from China Preliminary Determination* PDM at 16–18, unchanged in *Foil from China Final Determination.* We find that record evidence in this administrative review supports continuing to treat these companies as a single entity. *See* Memorandum, ''Zhongji Analysis for the Preliminary Results,'' dated concurrently with this notice.

[10] *See* Preliminary Decision Memorandum at the ''Separate Rate Determinations'' section for more details.

[11] On July 31, 2023, U.S. importer, Glenroy Inc withdrew its request for review of Galex Inc., Lotte Aluminium Co., Ltd., and Sama Aluminium Co Ltd.

[12] *See* Appendix II.

[13] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[14] *See Order.*

[15] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.''); *see also* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[16] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[17] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[18]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[19] Further, we request that interested parties limit their public, executive summary of each issue to no more than 450 words, not including citations. We intend to use the public, executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public, executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[20]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results of review in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results of this review, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[21] Commerce intends to issue assessment instructions to CBP no earlier than 35 days after date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For each individually examined respondent in this review whose weighted-average dumping margin in the final results of review is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce intends to calculate importer/customer-specific assessment rates.[22] Where the respondent reported reliable entered values, Commerce intends to calculate importer/customer-specific *ad valorem* assessment rates by aggregating the amount of dumping calculated for all U.S. sales to the importer/customer and dividing this amount by the total entered value of the merchandise sold to the importer/customer.[23] Where the respondent did not report entered values, Commerce will calculate importer/customer-specific assessment rates by dividing the amount of dumping for reviewed sales to the importer/customer by the total quantity of those sales. Commerce will calculate an estimated *ad valorem* importer/customer-specific assessment rate to determine whether the per-unit assessment rate is *de minimis;* however, Commerce will use the per-unit assessment rate where entered values were not reported.[24] Where an importer/customer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis,* or an importer/customer-specific *ad valorem* assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[25]

Pursuant to Commerce's refinement to its practice, for sales that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, Commerce will instruct CBP to liquidate the entry of such merchandise at the dumping margin for the China-wide entity.[26] Additionally, where Commerce determines that an exporter under review had no shipments of subject merchandise to the United States during the POR, any suspended entries of subject merchandise that entered under that exporter's CBP case number during the POR will be liquidated at the dumping margin for the China-wide entity.

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated antidumping duties, where applicable.

Cash Deposit Requirements

Commerce will instruct CBP to require a cash deposit for antidumping duties equal to the weighted-average amount by which the normal value exceeds U.S. price. The following cash deposit requirements will be effective for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register**, as provided by section 751(a)(2)(C) of the Act: (1) for the exporters listed in the table above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review for the exporter (except, if the dumping margin is *de minimis* (*i.e.,* less than 0.5 percent), then the cash deposit rate will be zero for that exporter); (2) for previously investigated or reviewed Chinese and non-Chinese exporters that are not listed in the table above but that have separate rates, the cash deposit rate will continue to be the exporter-specific rate established in the most recently completed segment of this proceeding; (3) for all Chinese exporters of subject

[16] *See* 19 CFR 351.309(c); see also 19 CFR 351.303 (for general filing requirements).

[17] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[18] *See* 19 351.309(c)(2) and (d)(2).

[19] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[20] *See APO and Service Procedures.*

[21] *See* 19 CFR 351.212(b)(1).

[22] *See* 19 CFR 351.212(b)(1).

[23] *Id.*

[24] *Id.*

[25] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

[26] *See NME Practice,* for a full discussion of this practice.

merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity (*i.e.,* 105.80 percent); [27] and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties has occurred, and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: April 26, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Review, In Part
V. Preliminary Determination of No Shipments
VI. Discussion of the Methodology
VII. Adjustment Under Section 777A of the Act
VIII. Currency Conversion
IX. Recommendation

Appendix II

Non-Selected Separate Rate Companies

1. Dong-IL Aluminium Co., Ltd.
2. Dongwon Systems Corp.
3. Eastern Valley Co., Ltd.
4. Granges Aluminum (Shanghai) Co., Ltd.
5. Shanghai Shenyan Packaging Materials Co., Ltd.
6. Suzhou Manakin Aluminum Processing Technology Co., Ltd.
7. Suzhou Manakin Trading Co., Ltd.

No Shipments

1. Anhui Maximum Aluminum Industries Company Ltd.
2. Anhui Zhongji Battery Foil Science & Technology Co., Ltd.
3. Manakin Industries, LLC
4. Xiamen Xiashun Aluminium Foil Co., Ltd.

Companies Determined To Be Part of the China-Wide Entity

1. Alcha International Holdings Limited
2. Aluminum Corporation of China Limited
3. Dingheng New Materials Co., Ltd.
4. Henan Mingtai Al. Industrial
5. Hunan Suntown Marketing Limited
6. Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd.
7. SAM–A Aluminum Co., Ltd.
8. Shandong Nanshan Aluminum Co., Ltd.
9. Shanghai Huafon Aluminium Corporation
10. Shanghai Shenhuo Aluminium Foil Co., Ltd
11. Shanghai Sunho Aluminum Foil Co., Ltd.
12. SK Global America Inc.
13. Suntown Technology Group Corporation Limited (Suntown Technology Group Co., Ltd.)
14. Walson (HK) Trading Co., Limited
15. Yinbang Clad Materials Co., Ltd.
16. Zhejiang Yongjie Aluminum Co., Ltd.

[27] *See Order.*

[FR Doc. 2024–09589 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC640]

Marine Mammals; Issuance of Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of permits.

SUMMARY: Notice is hereby given that individuals and institutions have been issued Letters of Confirmation (LOCs) for activities conducted under the General Authorization for scientific research on marine mammals. See **SUPPLEMENTARY INFORMATION** for a list of names and addresses of recipients.

ADDRESSES: The LOCs and related documents are available for review upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Amy Hapeman (LOC Nos. 21932, 25835, 27241, and 27326), Carrie Hubard (LOC Nos. 22081, 22291–01, 22856–01, 24045, and 25957), Erin Markin, Ph.D. (LOC Nos. 20519–01, 26784, and 27746), Shasta McClenahan, Ph.D. (LOC Nos. 21556 and 27369), Courtney Smith, Ph.D. (LOC Nos. 21134 and 26367), and Sara Young (LOC No. 25895 and 26643) at the email listed above or (301) 427–8401.

SUPPLEMENTARY INFORMATION: The requested LOCs have been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216). The General Authorization allows for bona fide scientific research that may result only in taking by Level B harassment of marine mammals. The following LOCs were issued between October 1, 2021, and December 31, 2023.

File No. 25895: Issued to Jacalyn Toth Sullivan, Stockton University, 101 Vera King Farris Drive, Galloway, New Jersey 08205 on October 29, 2021. This LOC authorizes unmanned aircraft system (UAS) surveys of harbor seals (*Phoca vitulina*) within Great Bay, New Jersey for count/survey, behavioral observation monitoring, photo-identification, and video purposes. The objectives of the study include determination of temporal patterns of harbor seal habitat use, population size, and shifts therein over time as the nearby wind farm becomes operational. The LOC expires on October 31, 2026.

File No. 20519–01: This LOC, held by Peggy Stap, Marine Life Studies, P.O. Box 884, Monterey, California 93942–0884, was extended on November 18, 2021, through April 30, 2022, while the holder's new application (File No. 25843) was in process. The LOC authorizes close approach of 18 species of cetaceans and 4 species of pinnipeds during vessel and UAS surveys for photo-identification, behavioral observations, passive acoustics, photogrammetry, and underwater photograph/video within the Monterey Bay National Marine Sanctuary. The objectives of the research would not change. The LOC was subsequently terminated on April 22, 2022, when a separate scientific research permit No. 25843 was issued (87 FR 29116, May 12, 2022).

File No. 22856–01: This LOC, held by Patricia Fair, Ph.D., South Carolina Aquarium, 100 Aquarium Wharf, Charleston, South Carolina 29401, was amended on August 30, 2021. The original LOC authorized vessel-based research for photo-identification, photogrammetry, and behavioral observations of bottlenose dolphins (*Tursiops truncatus*) in waters near Charleston, South Carolina. The amended LOC would allow researchers to use UAS as an additional platform to collect photographs and behavioral data. The objectives of the research would not

change. The LOC expires August 31, 2024.

File No. 25835: Issued to Tampa Bay Watch, Inc. (Principal Investigator [PI]: Savannah Gandee), 3000 Pinellas Bayway South, Tierra Verde, Florida 33715, on December 21, 2021. This LOC authorized authorize vessel-based surveys of bottlenose dolphins in the upper-middle regions of Tampa Bay, Florida, for behavioral observations, photo-identification, passive acoustic recordings, and photography/videography. The objectives of the study were to assess current life history parameters of the population, including abundance, social structure, and spatial distribution of the animals. The LOC was subsequently terminated on January 3, 2024, at the request of the PI due to the end of research efforts.

File No. 21134: This LOC, held by John Schacke, Ph.D., Georgia Ecology Dolphin Project, 223 Trace Lane, Commerce, Georgia 30530, was extended on January 14, 2022, until May 15, 2023. The LOC authorizes vessel-based research of bottlenose dolphins, including abundance surveys, behavioral observations, photography and video within coastal and estuarine waters of central Georgia. The objectives of the research would not change. The LOC was subsequently terminated on May 2, 2022, when a new LOC (No. 27241, see below) was issued.

File No. 26367: Issued to Shannon Gowans, Ph.D., Eckerd College, 4200 54th Avenue South, St. Petersburg, Florida 33711 on May 10, 2022. This LOC authorizes close approach, photo-identification, passive acoustic recordings, and behavioral observations of bottlenose dolphins, Atlantic spotted dolphins (*Stenella frontalis*), and rough-toothed dolphins (*Steno bredanensis*) during vessel surveys in Boca Ciega Bay and surrounding waters. The objectives of the study are to continue assessing population size, distribution, and changes to social structure of local bottlenose dolphins. The LOC expires on May 15, 2027.

File No. 25957: Issued to Ann Weaver, Ph.D., Good-Natured Statistics Consulting, P.O. Box 8732, St. Petersburg, Florida 33738 on May 11, 2022. This LOC authorizes close approach, photo-identification, and behavioral observations of bottlenose dolphins during vessel surveys in the John's Pass area, near St. Petersburg, Florida. The objectives of the study are to continue monitoring the abundance, distribution, birth rates, and behavior of bottlenose dolphins in the study area and identify changes, if any, related to coastal construction projects. The LOC expires on May 31, 2027.

File No. 26643: Issued to Kachemak Bay National Estuarine Research Reserve (PI: Deborah Boege Tobin, Ph.D.), University of Alaska Anchorage, 2181 Kachemak Drive, Homer, Alaska 99603 on October 15, 2022. This LOC authorizes vessel and aerial-based surveys to monitor harbor porpoise (*Phocoena phocoena*), assess site fidelity and habitat use, study foraging and social behavior, and compile a photo-identification catalog to track individuals in Kachemak Bay, Alaska. Dall's porpoise (*Phocoenoides dalli*), Eastern North Pacific gray whales (*Eschrichtius robustus*), killer whales (*Orcinus orca;* excluding the endangered Southern Resident Distinct Population Segment), minke whales (*Balaenoptera acutorostrata*), and harbor seals may also be encountered. The LOC expires on October 14, 2027.

File No. 26784: Issued to Gerard Pinto, Ph.D., Jacksonville University, Marine Science Research Institute, 2800 University Blvd. North, Jacksonville, Florida 32211 on October 19, 2022. This LOC authorizes vessel-based research surveys for close approach, photo-identification, behavioral observations, videography, passive acoustic recordings, and focal follows of bottlenose dolphins within the St. Johns River between Hart Bridge in Jacksonville and Shands Bridge in Green Cove Springs, Florida. The objective of the research is to continue a 10-year collaborative photo-identification study of the bottlenose dolphins in the St. Johns River in northeast Florida, focused on identifying individuals as well as dolphin biology, ecology, behavior, social structure, and health. The LOC expires on October 31, 2027.

File No. 21932: This LOC, held by Jessica Taylor, Outer Banks Center for Dolphin Research, 310 West Eden St., Kill Devil Hills, North Carolina 27948, was extended on January 13, 2023. This amended LOC authorizes vessel surveys, close approach, photo-identification, behavioral observations, and focal follows of bottlenose dolphins in the waters of northern North Carolina. The amended LOC expires on April 30, 2024.

File No. 21556: This LOC, held by Stephen McCulloch, Dolphins Plus Marine Mammal Responder, 31 Corrine Place, Key Largo, Florida 33037, was extended on April 26, 2023, until May 15, 2024. This LOC authorized vessel surveys, close approach, photo-identification, behavioral observations, and video recording of bottlenose dolphins in Southern Florida waters. This amendment extended the duration of the LOC until August 14, 2023. The LOC was subsequently terminated on August 14, 2023, when a new LOC (No. 27269, see below) was issued.

File No. 27241: Issued to John Schacke, Ph.D., Georgia Dolphin Ecology Project, 223 Trace Lane, Commerce, Georgia 30530, on May 2, 2023. This LOC authorizes research on bottlenose dolphins involving close approach during vessel surveys for count/survey, observations, photograph/video, and photo-identification within coastal and estuarine waters of central Georgia. The objective of the research is to describe basic population dynamics of the common bottlenose dolphin populations in the Central Georgia Estuarine Stock System. This includes evaluation of their abundance, distribution, residency, habitat utilization, and stock structure. The LOC expires on May 15, 2028.

File No. 27326: Issued to Nicole Mader, Dolphin Ecology Project, 106 Abbie Court, Stuart, Florida 34996, on June 12, 2023. This LOC authorizes research on bottlenose dolphins involving close approach during vessel surveys for counts, observations, monitoring, passive acoustic recordings, photography/videography, photo-identification, and focal follows within the St. Lucie River, Indian River Lagoon from the Stuart Causeway to Jupiter Inlet, and adjacent Atlantic coastal waters. The objectives of the research are to (1) identify dolphin seasonal residency or transient patterns on a small temporal scale, (2) monitor reproductive success and calf survival, (3) evaluate habitat use and behavior, and (4) document ranging patterns of dolphins into the nearshore coastal Atlantic Ocean of the Indian River Lagoon Estuarine System stock. The LOC expires on June 30, 2028.

File No. 27369: Issued to Stephen McCulloch, President, Protect Wild Dolphins Alliance, Inc., 307 Saint Thomas Avenue, Key Largo, Florida 33037, on August 14, 2023. This LOC authorizes research to estimate abundance, determine distribution patterns, assess habitat use, and evaluate site fidelity of bottlenose dolphins inhabiting the Upper Florida Keys. Authorized activities include close approach by vessel, for counts, photography, photo-identification, video recordings, behavioral observations, and underwater photography/videography by pole camera. The LOC expires on August 31, 2028.

File No. 22081: This LOC, held by Institute for Marine Mammal Studies (PI: Mobashir Solangi, Ph.D.), P.O. Box 207, Gulfport, Mississippi 39502, was extended on September 25, 2023. The

LOC authorizes vessel and aerial surveys using photo-identification, behavioral observations, photography, filming, and passive acoustic recordings to study bottlenose dolphins and other cetaceans, including Atlantic spotted, pantropical spotted (*Stenella attenuata*), and spinner (*Stenella longirostris*) dolphins, and pygmy sperm whales (*Kogia breviceps*) in select Mississippi and Louisiana waters. The extended LOC expires on December 1, 2024.

File No. 22291–01. Amended LOC issued to Barbara Brunnick, Ph.D., Palm Beach Dolphin Project, Taras Oceanographic Foundation, 5905 Stonewood Court, Jupiter, Florida 33468, on September 26, 2023. The LOC authorized vessel-based research for photo-identification, videography, and behavioral observations of bottlenose dolphins, Atlantic spotted dolphins, and ten other cetacean species in the nearshore and coastal waters of Palm Beach and Martin Counties, Florida. The amended LOC allows researchers to use unmanned aircraft systems as an additional platform to collect photographs, photogrammetry, and behavioral data. The LOC expires on June 30, 2025.

File No. 24045: This LOC, held by Jeremy Kiszka, Ph.D., Florida International University, 3000 NE 151st Street, Marine Science Building, Room 250D, North Miami, Florida 33181, was extended on January 30, 2024. The LOC authorizes vessel-based surveys for photo-identification, photography, videography, and behavioral observations of bottlenose and Atlantic spotted dolphins. Research may occur in Biscayne Bay and coastal waters of Broward and Miami Dade counties, Florida out to 200 m depth. The objectives of the research would not change. The extended LOC expires on February 10, 2025.

File No. 27746: Issued to Barbara Clark, Outer Banks Center for Dolphin Research, P.O. Box 7721, Kill Devil Hills, North Carolina 27948, on December 22, 2023. This LOC authorizes vessel surveys for close approach, photo-identification, and behavioral observations of bottlenose dolphins to monitor the presence, identity, ecology, and behavior of bottlenose dolphins within the sounds of North Carolina, including Roanoke Sound. The LOC expires on December 31, 2028.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: April 29, 2024.

Julia M. Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024–09531 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD870]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Citizen Science Operations Committee via webinar May 22, 2024.

DATES: The Citizen Science Operations Committee meeting will be held via webinar on Wednesday, May 22, 2024, from 9 a.m. until 4 p.m.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julia Byrd (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar. There will be an opportunity for public comment at the beginning of the meeting.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, Citizen Science Program Manager, SAFMC; phone: (843) 302–8439 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Citizen Science Operations Committee serves as advisors to the Council's Citizen Science Program. Committee members include representatives from the Council's Citizen Science Advisory Panel Pool, NOAA Fisheries' Southeast Regional Office, NOAA Fisheries' Southeast Fisheries Science Center, and the Council's Science and Statistical Committee. Their responsibilities include developing programmatic recommendations, reviewing policies, providing program direction/multi-partner support, identifying citizen science research needs, and providing general advice.

Agenda items include: Review of the Citizen Science Program's initial evaluation plan, including researchers sharing preliminary findings and committee discussion of those findings; a Citizen Science Program and Project update; the Citizen Science Program's project idea portal; and other business.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 29, 2024.

Claudia Stephanie Womble,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09537 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD916]

Schedule for Atlantic Highly Migratory Species Outreach Workshops; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public outreach workshops; correction.

SUMMARY: NMFS has rescheduled the Atlantic Highly Migratory Species (HMS) Outreach Workshop originally scheduled for May 2, 2024 in Arecibo, Puerto Rico. This workshop was announced in the **Federal Register** on April 29, 2024. NMFS has rescheduled the HMS Outreach Workshop for May 2, 2024 at a new time and location in Arecibo, Puerto Rico.

DATES: The date of the rescheduled workshop has not changed. The HMS Outreach Workshop in Arecibo, Puerto Rico will be held on May 2, 2024. See the **SUPPLEMENTARY INFORMATION** section for the specific time.

ADDRESSES: The HMS Outreach Workshop will be held in Arecibo, Puerto Rico. See the **SUPPLEMENTARY**

INFORMATION section for the specific location, which has changed.

FOR FURTHER INFORMATION CONTACT: Delisse Ortiz by email at *delisse.ortiz@noaa.gov* or by phone at 301–427–8530.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries are managed under the 2006 Consolidated HMS Fishery Management Plan and its amendments pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635.

Correction

In the **Federal Register** of April 29, 2023 (89 FR 33333, April 29, 2024) in FR Doc. 2024–09138 on page 33334, in the first column, the location of the fourth HMS Outreach Workshop listed under the heading ''*Workshop Dates, Times, and Locations*'' is corrected to read as follows:

4. May 2, 2024, 6 p.m.–8 p.m. AST, Club Náutico de Arecibo (Salón Comodoro), F8G2+7X4, 6680, Cambalache, Arecibo, PR 00612.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 29, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09592 Filed 4–30–24; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA) Availability for Public Comment on NCA6 Draft Prospectus; Call for Authors and Contributors, Technical Inputs; and Notice of Public Engagement

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of request for public comment on the Draft Prospectus of the Sixth National Climate Assessment, Call for Authors and Contributors, Call for Technical Inputs, and Notice of Planned Public Engagement.

SUMMARY: NOAA is publishing this notice on behalf of the U.S. Global Change Research Program (USGCRP), which seeks public comment on the proposed themes and framework of the Sixth National Climate Assessment (NCA6) as indicated by the Draft Prospectus presented in Part I. Based on input received from this notice, USGCRP will develop an annotated outline, which will be released for public comment at a later date. This notice also requests nominations for volunteer contributors and submission of technical inputs (Parts II and III) and provides notice of planned public engagement events (Part IV) for NCA6.

DATES: Comments and nominations must be submitted to the web address specified below and received by June 7, 2024, at 11:59 p.m.

ADDRESSES: Comments, nominations, and technical inputs from the public will be accepted electronically via the USGCRP Public Contribution System: *https://contribute.globalchange.gov* Instructions for submitting comments are available on the website. Submitters may enter text or upload files in response to this notice.

FOR FURTHER INFORMATION CONTACT: Chris Avery, (202) 419–3474, *cavery@usgcrp.gov,* U.S. Global Change Research Program.

SUPPLEMENTARY INFORMATION: The following **Federal Register** Notice contains four parts:

Part I is a high-level description of the proposed themes and framework of NCA6. Comment on these themes and framework is requested from the public.

Part II is a call for volunteers to participate in NCA6 as authors and technical contributors.

Part III requests submission of relevant research for authors to review and consider in developing NCA6.

Part IV provides a notice of planned public engagement events throughout the NCA6 development cycle.

In addition to the proposed themes and framework, this **Federal Register** Notice requests public comment on ways to make the assessment information accessible and useful to multiple audiences; specific types of information or formats that would be most useful to decision-makers; how to best describe risks and impacts to inform decisions, as well as potential opportunities to reduce those risks and impacts; new topics or new approaches to topics addressed in previous assessments; overarching themes that NCA6 should consider addressing; and other relevant input.

The Global Change Research Act (GCRA) of 1990 mandates that the U.S. Global Change Research Program (USGCRP) deliver a National Climate Assessment (NCA) to Congress and the President not less frequently than every four years that ''(1) integrates, evaluates, and interprets the findings of the Program; (2) analyzes the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity; and (3) analyzes current trends in global change, both human-induced and natural, and projects major trends for the subsequent 25 to 100 years.''

To date, five NCAs have been released. The first NCA was published in 2000, and the second was published in 2009. The third NCA was published in 2014, and the fourth was released in two volumes and completed in November 2018. The most recent, the fifth NCA, was released in November 2023, and can be found at *https://nca2023.globalchange.gov.*

NCA6 development will be transparent and inclusive, offering opportunities for diverse public participation throughout the process. The production and review processes are designed to result in a report that is authoritative, timely, relevant, and policy-neutral; valued by authors and users; accessible to the widest possible audience; and fully compliant with the GCRA.

I. Overarching Themes for NCA6 (Draft Prospectus)

NCA6 will encompass a number of overarching themes and perspectives that respond to needs and gaps identified by previous assessments. We seek inputs on potential overarching themes for the NCA6 report, including on the topics listed below:

Identification of advancements or improvements, relative to previous assessments, in scientific understanding of human-induced and natural processes of global change and the resulting implications for the U.S.

Characterization of current and future risks associated with global change, with quantifiable metrics such as indicators and projections where possible, and with the needs of different sub-national geographies and multiple audiences in mind.

Examining trends and developments in adaptation; adaptation options and effectiveness of adaptation efforts; approaches for monitoring adaptation progress including indicators and metrics.

Further exploration of how people understand the drivers, risks, and impacts of climate change; how changes in climate affects national security, society, and different people or groups of people living within the U.S.; and how people behave in response to climate-induced change.

Identification of populations living in the U.S. at higher risk of climate impacts, perspectives on equity and

environmental justice in connection with domestic mitigation and adaptation actions, exploration of the socio-economic impacts from these actions, and the role of frontline communities in the country's response to climate change.

Better understanding of sources and trends in U.S. and global greenhouse gas emissions; new strategies for mitigation, effectiveness of mitigation efforts, and new technology pathways for reaching different emissions targets; tradeoffs in different response options; and any other response-related questions that might support decision-making.

We seek comments on these proposed overarching themes, as well as suggestions for potential additional overarching themes.

Proposed Framework for NCA6

What follows is a proposed high-level framework intended to guide the scope and content for NCA6. Public comments are sought on all aspects of this proposed framework.

The proposed framework includes the following topics:

(A) Introduction and context for NCA6
(B) Foundational physical, social, and biological drivers of past and future climate change
(C) Climate risks and impacts to human health and well-being, social systems, and environments
(D) Regional and, where possible, sub-regional analyses within the United States
(E) Information needed to inform climate change mitigation and adaptation actions, increase resilience, and reduce risks
(F) Updates to the NCA Atlas and other climate services tools

This framework presents the anticipated scope and content of NCA6; it is not an indicator of the final structure of the report. Comments on these general topics, as well as any key scientific advances within a topic, are welcomed.

A. Introduction and Context for NCA6

Considerations of context and scope of NCA6 include the overarching themes noted above as well as the following:

NCA's relationship to complementary domestic and international assessment efforts.

Advancements in science or scientific approaches since NCA5 and discussion of the associated uncertainty, including assessments completed or in progress after publication of NCA5, and in particular those under the auspices of USGCRP (*e.g.,* the National Nature Assessment).

The geographic and temporal scope (*i.e.,* historic to the next 25 to 100 years).

Risks to interconnected natural, built, and social systems, and the potential for cascading or compound impacts of global change.

Terms and their definitions used to describe confidence and uncertainty levels associated with key statements and findings (and accompanying traceable accounts), which may be similar to those used in NCA5.

We seek public comment on the proposed introductory and contextual material described above for NCA6.

B. Foundational Physical, Social, and Biological Drivers of Past and Future Climate Change

NCA6 will assess the state of scientific evidence regarding the social, physical, and biological drivers of global change, with an emphasis on advances in knowledge since NCA5, including the following:

Changing global and national conditions that influence (1) drivers of climate change, namely the activities that lead to emissions and atmospheric buildup of greenhouse gas concentrations; and (2) factors that affect communities' resilience and vulnerability, such as demographic and land-use changes, behavioral changes, advances in technology, and economic development.

Observations of changes in climate-related phenomena at global, national, and subnational scales, such as atmospheric composition, radiative forcing, temperature, precipitation, climate variability, large-scale climate modes (*e.g.,* El Niño events), drought, wildfire, floods and associated hydrologic events (*e.g.,* streamflow, snowpack), sea-level rise and other physical ocean changes, biogeochemistry of land and marine systems, ocean acidification, extreme heat, and storms (*e.g.,* hurricanes), atmospheric rivers, polar changes (including permafrost and land-ice dynamics), and ice-sheet dynamics; and attribution of social, physical, and biophysical processes to human activities.

Future projections of changes in Earth system processes based on modeling results of the Coupled Model Intercomparison Project (CMIP). Treatment of future scenarios, and associated risks and impacts, will emphasize the most recent modeling data (*i.e.,* CMIP6), with CMIP5 and other future scenarios included as determined by the available sources of information.

Scientific understanding of observed and future extremes, including the attribution of an extreme event (intensity, duration, frequency, etc.) to climate change-related causes and potential tipping points or other potential outcomes that may have a low probability of occurring, but could be extremely damaging or highly beneficial to the U.S. were they to occur.

We seek public comment on the proposed physical, social, and biological science framing described above for NCA6.

C. Climate Change Risks and Impacts to Human Health and Well-Being, Social Systems, and Environments

The GCRA of 1990 requires that the NCA analyze ''the effects of global change on the natural environment, agriculture, energy production and use, land and water resources, transportation, human health and welfare, human social systems, and biological diversity.'' NCA6 will provide national-level overviews of observed and potential risks and impacts under a range of scenarios in these key areas of concern for people and the environment, with supporting regional information, as described under Part D.

To better understand global change, non-climatic trends (*e.g.,* population changes) will be discussed to provide a broader context within which the effects of climate change can be understood. Current and future risks, impacts, and benefits will be identified in each of these topic areas, using quantifiable metrics where possible. The impact of extreme events will be addressed where possible. In addition, potential mitigation, adaptation, and resilience measures to reduce risks will be described, to the extent these are identified in available sources of information.

In addition to coverage of these mandated topics, the following additional specific areas are under consideration for inclusion in NCA6: land cover and land-use change; forests; ecosystems and ecosystem services; coasts; ocean ecosystems; marine resources; built environment; urban and rural systems; air quality; effects on Tribal and Indigenous communities; economics; and international effects, in particular those that may raise environmental, humanitarian, trade, or public safety and security issues for the United States. It is worth noting that NCA6 may choose to reduce its coverage of topics that are assessed in other products (such as the National Nature Assessment), depending on the assessment findings of the author teams.

NCA6 will prioritize use of data and research that include full geographic coverage of the entire nation, inclusive

of Alaska, Hawai'i, U.S.-Affiliated Pacific Islands, and the U.S. Caribbean.

We seek public comment on the proposed areas of focus for NCA6 as described above and welcome input on other topics that should be considered for inclusion. Please note that topics listed in the Draft Prospectus or submitted as comments may or may not result in a standalone chapter or feature; development of the table of contents is at the discretion of the NCA6 Federal Steering Committee.

D. Regional Analyses Within the United States

This section will describe sub-national, regional-level perspectives for each of the areas identified in Part C, allowing for discussion of topics of interest to each region.

The proposed regional analyses for NCA6 will follow the model of NCA5, which included the following regions of the United States: Northeast, Southeast, U.S. Caribbean, Midwest, Northern Great Plains, Southern Great Plains, Northwest, Southwest, Alaska, and Hawai'i and U.S.-Affiliated Pacific Islands (see *https://nca2023.globalchange.gov/chapter/front-matter#fig-1*). Areas of focus will vary across regions based on the availability of research and the regional identification of needs.

As appropriate and where available, NCA6 will also highlight information at the state, city, Tribal, and territory level, as well as urban and rural case studies to showcase climate trends, potential risks, and mitigation, adaptation, and resilience action with local specificity.

We seek public comment on the proposed level of detail to be provided at regional scales, sectors, or topics to focus on within particular regions, and overarching themes that should inform the regional analyses within NCA6.

E. Information Needed To Support Climate Change Mitigation, Adaptation, Resilience, and Risk Reduction

NCA6 will identify needs and opportunities for mitigation, adaptation, and resilience measures and planning in the face of observed and projected changes in climate. NCA6 will not evaluate nor recommend specific policy measures, actions, instruments, or mechanisms to deliver or incentivize either adaptation or mitigation responses at any level of government. Rather, the intention of NCA6 is to inform mitigation, adaptation, and resilience needs, planning, and actions across the nation. Scientific assessment of mitigation, adaptation, and resilience needs and opportunities will also be drawn from relevant information from Parts B, C, and D as outlined above, including evidence of successful measures, and discussed in the context of the research topics described below.

Review of the following is proposed for inclusion in NCA6:

Recent information on economic drivers of emissions; social and economic impacts of climate change across sectors and regions at different levels of warming.

Recent information on the potential for reducing greenhouse gas emissions, adapting to climate impacts, and building climate resilience through various solutions and strategies. This includes an assessment of the evidence regarding the effectiveness of these solutions and strategies.

Recent information describing case studies (see Part D), where relevant.

The NCA also underpins U.S. government decision-support tools and resources such as the Climate Mapping for Resilience and Adaptation (CMRA) portal, and U.S. Climate Resilience Toolkit. Moreover, the NCA is a significant climate service for both producers and users in their mitigation, adaptation, and resilience work.

We seek public comment on the proposed framing of information in NCA6 needed to support climate change mitigation, adaptation, resilience, and risk reduction, connections between NCA6 and other U.S. government decision support tools, and how NCA6 may inform development and delivery of climate services (see Part F).

F. Updates to NCA Atlas and Other Climate Services

The incorporation of NCA information into U.S. government decision-support tools and other climate services has proven to be an effective way of ensuring NCAs are both useful and usable. USGCRP will maintain and expand the NCA Atlas as NCA6 develops, in addition to maintaining and expanding other existing support tools (see Part E). USGCRP will also seek to identify needs and opportunities for new climate services or connections between NCA and other relevant tools. This could include assessments of available climate services, especially as they relate to adaptation, resilience, and mitigation efforts. Gaps and opportunities could be a result of governance challenges and/or modeling/scientific understanding. Suggestions for other decision-support tools and services are welcomed.

As with previous assessments, appendices and front matter sections will provide additional background, context, and detail on the development of NCA6. Topics currently planned for inclusion include report process details, legal mandates and requirements, tools, and technical inputs. Suggestions for other appendix topics are requested.

We seek public comment on all aspects of the anticipated scope and content of this framework for NCA6, as described above.

Responses: Response to this Request for Comment is voluntary. Respondents need not reply to all questions or topics. Responses may be used by the U.S. Government for program planning on a non-attribution basis. NOAA therefore requests that no business proprietary information or copyrighted information be submitted in response to this Request for Comment. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

II. Call for Authors and Contributors

NCA6 will be written by a group of volunteers with expertise in topics relevant to climate science and global change. Nominations are sought for authors with pertinent subject matter expertise, proficiency, or relevant background, including Indigenous Knowledge holders, in at least one of the topics delineated in the draft prospectus (Part I). Nominations are encouraged from all governmental and nongovernmental sectors.

The NCA6 Federal Steering Committee (FSC) recognizes the value of Indigenous Knowledge that Tribal Nations and Indigenous peoples have gained and passed down from generation to generation and recognizes Indigenous Knowledge as one of many important bodies of knowledge that can contribute to NCA6. The FSC understands that multiple lines of evidence or ways of knowing can lead to better-formed assessments and encourages nominations of Indigenous Knowledge holders for all NCA6 participant roles.

Submissions must document that nominees have demonstrated backgrounds such that they could contribute to the development of a robust assessment as subject matter experts in one or more of the topics described in the Draft Prospectus (Part I of this FRN) above. In addition, individuals interested in being considered for chapter leadership positions should have experience with leading collaborative teams under deadlines.

Authors volunteering to assist in writing NCA6 are providing an important service to the United States. In addition to providing an opportunity to inform policy, participation in NCA6 will allow authors to expand their professional networks and visibility,

and to explore opportunities to create derivative products.

The Federal Government will not provide financial compensation for these roles. The Federal Government is anticipated to provide travel costs to authors to attend meetings if requested for NCA6; however, this is not guaranteed. Formal acknowledgment of participant contributions will be provided to each author and their institution as requested.

NCA6 will attempt to address the full breadth of each topic and seeks a suitably diverse author pool, including Indigenous Knowledge holders, biophysical and social scientists, engineers, planners, and traditionally underrepresented groups. Selection criteria for all author positions will consider expertise, disciplinary background, career status, diversity, and geographic representation.

Participant Roles

Nominees may be invited to serve as Chapter Lead Authors, Graphics Development Leads, Authors, or Technical Contributors to NCA6.

A Federal Coordinating Lead Author (CLA) selected by the Federal Steering Committee (FSC) will serve as a liaison between the author team and federal agencies.

Chapter Leads (CLs) oversee chapter development by selecting authors, managing author teams, delegating chapter writing assignments, and providing drafts of the chapter to the CLA. CLs are closely involved with the writing process, working to ensure that the content of the chapter is consistent across sections and drafts are delivered on time. CLs will, with input and guidance from the FSC and CLA, establish author teams comprising federal and non-federal experts. Only non-federal experts may serve as CLs. Persons selected as CLs will be informed after the close of the nominations window.

The Graphics Development Lead is a new role introduced for NCA6. Graphics Leads will be a full author on the chapter team and will be responsible for leading and managing the development of all graphics within their assigned chapter. They will work directly with USGCRP staff and the NOAA Technical Support Unit throughout the process to ensure that well-designed informative graphics are developed alongside the text of the chapter.

Technical Contributors are invited by CLs to contribute to chapters for discrete, specific content, such as a case study or a figure, on an as-needed basis. Technical Contributors are not chapter authors and may be either federal or non-federal employees. Technical Contributors may be brought on later in the NCA6 development process as specific expertise is identified.

Eligible nominees not selected as Chapter Leads will be considered for other chapter roles as appropriate. For more information on author roles, see *https://www.globalchange.gov/nca6*.

Nomination Process

In developing NCA6, USGCRP will follow the principles of a use-inspired, knowledge-informed assessment, shaped by both the potential uses of the final products and by science and other forms of knowledge. USGCRP recognizes the importance of lived experiences and acknowledges Indigenous Knowledge as an important form of evidence. Across all phases of NCA6, USGCRP aims to be inclusive, represent diverse perspectives, and create products that are accessible to the widest possible audience.

Responses to this request for nominations for authors must be submitted by the closing of this FRN. The nomination forms can be accessed via *https://www.globalchange.gov/notices*. Interested persons may nominate themselves or third parties for these roles, and individuals may submit multiple nominations.

Each nomination must include (1) the nominee's full name, title, institutional affiliation, and contact information; (2) the nominee's area(s) of expertise; (3) the proposed NCA6 topic(s) (see Draft Prospectus in Part I above) for which the nominee is qualified; (4) a short description of the nominee's qualifications relative to contributing to the report; and (5) a current CV [maximum length four (4) pages].

All interested members of the public are encouraged to volunteer themselves for consideration. Nominations with missing information, or for nominees who do not meet the eligibility requirements above, may not be considered.

Expertise Sought

In accordance with the GCRA, USGCRP seeks nominations with expertise in the areas of climate/Earth system science, as well as sectoral, issue-specific, and regional impacts. This includes expertise in the following broad topic areas (subject to change):

Climate/Earth system science expertise to integrate, evaluate, and interpret the latest scientific findings; discuss the associated uncertainties; analyze current trends in global change; and project major trends for the subsequent 25 to 100 years.

Sectoral and issue-specific impacts expertise, including in the social sciences, to analyze the effects of global change on the natural environment (including terrestrial, aquatic, and marine ecosystems); agriculture (including food and food production); energy production and use; land and water resources (including land cover/land-use change, forests, coasts, oceans, and terrestrial/marine resources); transportation; human health and welfare (including air quality); human social systems (including the built environment, urban/rural systems, cities, and economics); biological diversity; Tribes and Indigenous peoples; and response.

Regional expertise that integrates across relevant natural and social science areas for the NCA regions (available at *https://www.globalchange.gov/nca5*).

Response expertise relevant to NCA6, including (but not limited to) mitigation, adaptation, resilience, or other relevant scientific topics.

Any other relevant climate services-related topic or skill set not listed above, including (but not limited to) engineering, planning, architecture, finance, business.

Further, authors are welcome to nominate themselves for topics not listed above that are consistent with the GCRA mandate.

In addition to technical knowledge, USGCRP seeks nominees with expertise that would be useful for developing an NCA chapter. These skills include (but are not limited to) the following:

Clear and effective scientific writing, especially for a non-technical audience.

Graphic design experience, such as developing data-focused graphics that are clear and effective, development of infographics, or downscaling modeling visualization.

Team management experience, including overseeing the work of multiple technical experts to a central project.

Synthesis and assessment projects, especially across multiple research disciplines and types of technical inputs.

Conditions of Participation

All participation in and contributions to the NCA will be without compensation and will be potentially included in the publicly released NCA. By voluntarily participating in the NCA, you acknowledge the following:

1. Participation in the NCA means facilitating the development of the NCA, contributing new work to the NCA, or contributing preexisting work for the NCA. Any such work will be

incorporated into the NCA at the Federal Government's discretion, including the possibility of modification, without any compensation and without redaction under the Freedom of Information Act (FOIA) or otherwise.

2. All contributions to the NCA of text and original figures (those newly created for NCA and not previously published) will be released under the Creative Commons 1.0 Universal Public Domain Dedication (CC0 1.0). Such contributions will not be protected by copyright or other intellectual property rights. Data, algorithms/models, and software code used to create or support the creation of text and original figures will also be publicly released in connection with the NCA. In some cases, such data, algorithms/models, and software code may be subject to copyright restrictions prohibiting both their use for commercial purposes and the creation of derivative works, such as CC BY–NC–ND 4.0, but any such restrictions may not prohibit their use for the purpose of reproducing results.

3. Participants assume any and all risks associated with participation in the NCA. By participating, participants inherently waive all claims against the Federal Government and its related entities, except for claims based on willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits (whether direct, indirect, or consequential) arising from participation in the NCA.

4. By participating, participants agree to indemnify the Federal Government in the event that it suffers liability or damages as a result of its use of the contribution.

Submission of a nomination is entirely voluntary and submitters are encouraged to ensure they understand the scope of the obligation before volunteering. More information, as well as information on asking questions beforehand, at *https://www.globalchange.gov/nca6*.

III. Call for Technical Inputs

In addition, this request presents an opportunity to submit relevant scientific/technical inputs to inform the assessment. Any interested parties are encouraged to submit relevant sources of information (*e.g.,* papers, articles, reports, Indigenous Knowledge, and other local knowledge) for the NCA6 author teams to consider and assess for their work. Technical submissions will be accepted electronically via the USGCRP Public Contribution System: *https://contribute.globalchange.gov* Instructions for submitting technical inputs are available on the website. Submitters may enter text or upload files in response to this notice.

After the closure of this FRN, submissions of technical inputs will still be accepted throughout the NCA6 development process. This call for technical inputs is expected to remain open until the close of the NCA6 call for public comments on the NCA6 Third Order Draft, anticipated to end in early 2027. Additional information on the process for submitting technical inputs can be found after the closure of this FRN on USGCRP's website. See *https://www.globalchange.gov/nca6* for more information.

Response to this call for technical inputs is voluntary.

IV. Notice of Planned Public Engagement Opportunities for NCA6

Multiple opportunities for public engagement to inform NCA6 will be presented throughout the report's development. The following planned public engagement schedule is presented to notify the public of these coming opportunities. The time ranges proposed are subject to change based on the timing of various development stages for NCA6.

Public call for comments on the Draft Prospectus (Q2 2024)

Public call for authors and technical inputs (Q2 2024)

Public comment on NCA6 annotated outline (Q3 2025)

Public engagement workshops and webinars (Q3 2025)

Public call for art (Q2 2026)

Public call for Review Editors (Q3 2026)

Public comment on NCA6 Third Order Draft (Q4 2026 and Q1 2027)

National Academies of Sciences, Engineering, and Medicine peer review of NCA6 Third Order Draft (Q4 2026 and Q1 2027)

Interested parties are invited to participate in these public engagement opportunities to ensure robust public input to NCA6. Specific dates and locations for all engagements will be provided on *https://www.globalchange.gov/notices*. Members of the public may also sign up to receive updates through USGCRP's bimonthly newsletter at *https://www.globalchange.gov/newsletter-signup*.

David Holst,

Chief Financial Officer and Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2024–09575 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Application for Commercial Fisheries Authorization Under Section 118 of the Marine Mammal Protection Act

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before July 1, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0293 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Jaclyn Taylor, National Marine Fisheries Service, Office of Protected Resources, 1315 East West Hwy., Bldg. SSMC3, Silver Spring, MD 20910–3282, 301–427–8402 or *Jaclyn.Taylor@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The National Marine Fisheries Service's (NMFS) Office of Protected Resources sponsors this information collection and is requesting renewal of the currently approved collection.

Section 118 of the Marine Mammal Protection Act (MMPA) requires any commercial fisherman operating in Category I and II fisheries to register for a certificate of authorization that will allow the fisherman to take marine

mammals incidental to commercial fishing operations. Category I and II fisheries are those identified by NOAA as having either frequent or occasional takings of marine mammals. All states have integrated the NMFS registration process into the existing state fishery registration process and vessel owners do not need to file a separate federal registration. If applicable, vessel owners will be notified of this simplified registration process when they apply for their state or Federal permit or license. A valid certificate of authorization protects the vessel owner from prosecution under the MMPA for violation of the moratorium on taking marine mammals. The information needed to register or update a commercial fishery authorization is found at 50 CFR 229.4

II. Method of Collection

Fishermen's information is imported directly into the Marine Mammal Authorization Program (MMAP) from their state. If they do not have a state or Federal fishery permit or license, fishermen can request a MMAP registration form (OMB no. 0648–0293) from their NMFS regional office and mail or email the registration form.

III. Data

OMB Control Number: 0648–0293.
Form Number(s): None.
Type of Review: Regular submission [extension of a current information collection].
Affected Public: Individuals or households; Business or other for-profit organizations.
Estimated Number of Respondents: 100.
Estimated Time per Response: Initial registration 15 minutes.
Estimated Total Annual Burden Hours: 25 hours.
Estimated Total Annual Cost to Public: $2,555 in recordkeeping/reporting costs and application fees.
Respondent's Obligation: Required for participants in Category I and II fisheries to lawfully take marine mammals' incidental to fishing operations.
Legal Authority: 16 U.S.C. 1361 *et seq.;* MMPA.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–09484 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD903]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit (EFP) renewal application from the New Hampshire Fish and Game Department contains all of the required information and warrants further consideration. The EFP would allow federally permitted fishing vessels to fish outside fishery regulations in support of exempted fishing activities proposed by the applicant. Regulations under the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed EFPs.

DATES: Comments must be received on or before May 17, 2024.

ADDRESSES: You may submit written comments by the following method:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''NHFG Early Benthic-Phase Lobster Trap EFP''.

All comments received are a part of the public record and may be posted for public viewing in *https://www.noaa.gov/organization/information-technilogy/foia-reading-room* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''anonymous'' as the signature if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Christine Ford, Fishery Management Specialist, *Christine.Ford@noaa.gov,* (978) 281–9185.

SUPPLEMENTARY INFORMATION: The New Hampshire Fish and Game Department (NHFG) submitted a complete application for an EFP to conduct commercial fishing activities that the regulations would otherwise restrict. The EFP would allow NHFG to continue pilot testing of early benthic-phase (EBP) lobster traps, designed to target juvenile lobsters between 15- and 60-millimeter (mm) carapace length, to determine their feasibility for broader use in lobster surveys. This EFP would exempt the participating vessels from the Federal regulations in table 1:

TABLE 1—REQUESTED EXEMPTIONS

CFR citation	Regulation	Need for exemption
50 CFR 697.21(c) and § 697.21(d)	Gear specification requirements	To allow for the use of modified traps with no escape vents or ghost panels.

TABLE 1—REQUESTED EXEMPTIONS—Continued

CFR citation	Regulation	Need for exemption
§ 697.19	Trap limit requirements	To allow for four additional traps per vessel (20 total).
§ 697.19(j)	Trap tag requirements	To allow for the use of four untagged traps per vessel (20 total).
§§ 697.20(a)(7), 697.20(a)(8), 697.20(b)(5), 697.20(b)(6), 697.20(d), and 697.20(g).	Possession restrictions	To allow for onboard biological sampling of undersized, oversized, v-notched, and egg-bearing lobsters.
§ 697.21(a)	Gear identification and marking requirements.	To allow for the use of four unmarked traps per vessel (20 total).

TABLE 2—PROJECT SUMMARY

Project title	Testing an EBP lobster trap on Georges Bank.
Project start	06/15/2024.
Project end	06/14/2025.
Project objectives	To continue testing an early-benthic-phase lobster trap, which targets lobsters between 15- and 60-mm carapace lengths, to determine its feasibility for broader use in lobster surveys.
Project location	Offshore Gulf of Maine & Georges Bank; Statistical Areas 513, 522, 525, 526, 537, 561, and 562.
Number of vessels	Up to 5.
Number of trips	500.
Trip duration (days)	Up to 8.
Total number of days	Up to 4,000.
Gear type(s)	Trap/pot (modified—see project narrative).
Number of tows or sets	Up to 4 per trip; up to 2,000 total.
Duration of tows or sets	~4 days.

Project Narrative

The participants would place four EBP traps on two of their existing trawls (two EBP traps per trawl) and haul them up to twice per trip (for a total of up to four hauls per trip) during the course of the vessel's normal fishing activity. The EBP traps are 80-centimeter (cm) square traps based on a modified crawfish trap. They have four square openings, measuring less than 2 inches (5.08 cm), which lead to ramps that drop the lobsters into a baited kitchen. Inside the traps, there are additional ramps that lead the lobsters to four cylindrical parlors with vertical openings. The traps are attached to cement runners that provide weight and maintain proper orientation. The crews would rig the EBP traps within Atlantic Large Whale Take Reduction Plan-compliant commercial trawls, resulting in no additional end lines. Each vessel would fish four traps above their allocation, but would remain within the universal Area 3 trap cap. At each haul, crews would record, and immediately release, all bycatch and measure, sex, and release all lobsters from the EBP trap. They would also sample catch in two standard traps within the trawl as control data. They would land and sell the legal catch from the standard traps.

The goal of this project is to test the selectivity of the EBP trap (versus ventless traps that often catch eel and crab), and the scalability of its use. If successful, EBP traps could be used in lobster surveys to provide information about larval-settlement patterns and juvenile nursery grounds.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 26, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–09502 Filed 5–1–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Federal Advisory Committee Meetings

AGENCY: Under Secretary of Defense for Research and Engineering (USD(R&E)), Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meetings.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meetings of the Defense Science Board (DSB) will take place.

DATES: Closed to the public Wednesday, June 26, 2024 from 8 a.m. to 5 p.m.; closed to the public Thursday, June 27, 2024 from 8 a.m. to 4 p.m.; closed to the public Wednesday, July 24, 2024 from 8 a.m. to 5 p.m.; closed to the public Thursday, July 25, 2024 from 8 a.m. to 4 p.m.

ADDRESSES: The address of the closed meetings is 4075 Wilson Blvd., Suite 300, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth J. Kowalski, Designated Federal Officer (DFO): (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *elizabeth.j.kowalski.civ@mail.mil,* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: These meetings are being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the

''Government in the Sunshine Act''), and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR).

Purpose of the Meetings: The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will discuss the 2024 DSB Summer Study on Advanced Capabilities for Potential Future Conflict and classified strategies for continued development of symmetric and asymmetric capabilities.

Agenda: The meeting will begin on Wednesday, June 26, 2024 at 8 a.m. Ms. Betsy Kowalski, DSB DFO, and Dr. Eric Evans, DSB Chair, will provide opening remarks and a classified overview of the objectives of the 2024 Summer Study on Advanced Capabilities for Potential Future Conflict. Next, the DSB will meet to discuss classified strategies that best enable DoD's continued development of symmetric and asymmetric capabilities that will characterize future conflicts, including periodic breaks. The meeting will adjourn at 5 p.m. On Thursday, June 27, 2024, starting at 8 a.m., the DSB will continue to meet to discuss classified strategies that best enable DoD's continued development of symmetric and asymmetric capabilities that will characterize future conflicts, including periodic breaks. The meeting will adjourn at 4 p.m. On Wednesday, July 24, 2024, the meeting will begin at 8 a.m. Ms. Betsy Kowalski, DSB DFO, and Dr. Eric Evans, DSB Chair, will provide opening remarks and a classified overview of the objectives of the 2024 Summer Study on Advanced Capabilities for Potential Future Conflict. Next, the DSB will meet to discuss classified strategies that best enable DoD's continued development of symmetric and asymmetric capabilities that will characterize future conflicts, including periodic breaks. The meeting will adjourn at 5 p.m. On Thursday, July 25, 2024, starting at 8 a.m., the DSB will continue to meet to discuss classified strategies that best enable DoD's continued development of symmetric and asymmetric capabilities that will characterize future conflicts, including periodic breaks. The meeting will adjourn at 4 p.m.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, the DoD has determined that the DSB meetings will be closed to the public. Specifically, the USD(R&E), in consultation with the DoD Office of the General Counsel, has determined in writing that the meetings will be closed to the public because they will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meetings to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the USD(R&E).

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section at any point; however, if a written statement is not received at least three calendar days prior to a meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: April 26, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09571 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0089]

Submission for OMB Review; Comment Request

AGENCY: Office of the Secretary of Defense, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Reginald Lucas, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Generic Clearance for Improving Customer Experience (OMB Circular A–11, Section 280 Implementation); OMB Control Number 0704–0595.

Type of Request: Extension.

Number of Respondents: 300,000.

Responses per Respondent: 1.

Annual Responses: 300,000.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 50,000.

Needs and Uses:

A. Purpose

Whether seeking a loan, Social Security benefits, veteran's benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in

nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. DoD will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on performance.gov to help build transparency and accountability of Federal programs to the customers they serve.

Method of Collection:

DoD will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. DoD may also utilize observational techniques to collect this information.

B. Annual Reporting Burden

Affected Public: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09556 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0046]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel & Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the OUSD(P&R) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 1, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Federal Voting Assistance Program, Department of Defense, 4800 Mark Center Drive, Suite 05E22, Alexandria, VA 22350–5000, Brianna Paul, (571)–545–3996.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Federal Post Card Application (FPCA); SF76; OMB Control Number 0704–0503.

Needs and Uses: The Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. 203, requires the Presidential designee (Secretary of Defense) to prescribe an official form containing an absentee voter registration and ballot request application for use by the States to permit absent uniformed services voters and overseas voters to participate in general, special, primary and runoff elections for Federal office. The authority for the States to collect personal information comes from UOCAVA. The burden for collecting this information resides in the States. The Federal government neither collects nor retains any personal information associated with this form.

The collected information will be used by State and local election officials to process uniformed service members, spouses and overseas citizens who submit their information to register to vote or receive an absentee ballot. The collected information will be retained by election officials to provide election materials, including absentee ballots, to the uniformed services, their eligible family members and overseas voters during the form's eligibility period provided by State law. No information from the Federal Post Card Application (FPCA) is collected or retained by the Federal government. The FPCA is completed in hardcopy or via the Federal Voting Assistance Program's (FVAP) online assistant (*fvap.gov*), and then submitted by the voter to an Election Official through mail, email, or fax (depending on State instructions). Per the law, FVAP regularly reaches out to UOCAVA citizens in order to raise awareness of its voting assistance services, primarily via its website, *FVAP.gov.*

Affected Public: Individuals; State and Local Governments.

Annual Burden Hours: 300,000.

Number of Respondents: 1,200,000.
Responses per Respondent: 1.
Annual Responses: 1,200,000.
Average Burden per Response: 15 minutes.
Frequency: On Occasion.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09558 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0045]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel & Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the OUSD(P&R) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 1, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Federal Voting Assistance Program, Department of Defense, 4800 Mark Center Drive, Suite 05E22, Alexandria, VA 22350–5000, Brianna Paul, (571) 545–3996.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Federal Write-In Absentee Ballot; Standard Form 186; OMB Control Number 0704–0502.

Needs and Uses: The Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA), 52 U.S.C. 203, requires the Presidential designee (Secretary of Defense) to prescribe an official backup ballot for use by the States to permit absent uniformed services voters and overseas voters to participate in general, special, primary and runoff elections for Federal office. The authority for the States to collect personal information comes from UOCAVA. The burden for collecting this information resides in the States. The Federal government neither collects nor retains any personal information associated with these forms.

The collected information will be used by State and local election officials to process uniformed service members, spouses and overseas citizens who submit their information to register to vote or receive an absentee ballot. The collected information will be retained by election officials to provide election materials, including absentee ballots, to the uniformed services, their eligible family members and overseas voters during the form's eligibility period provided by State law. No information from the Federal Write-In Absentee Ballot (FWAB) is collected or retained by the Federal government. The FWAB is completed in hardcopy or via the Federal Voting Assistance Program's (FVAP) online assistant (*fvap.gov*), and then submitted by the voter to an Election Official through mail, email, or fax (depending on State instructions). Per the law, FVAP regularly reaches out to UOCAVA citizens to raise awareness of its voting assistance services, primarily via its website, *FVAP.gov.*

Affected Public: Individuals or households; Businesses or other for-profit; Not-for-profit Institutions; Farms, Federal Governments; State, Local or Tribal Government.

Annual Burden Hours: 300,000.
Number of Respondents: 1,200,000.
Responses per Respondent: 1.
Annual Responses: 1,200,000.
Average Burden per Response: 15 minutes.
Frequency: On Occasion.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09554 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Military Personnel Testing; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following meeting of the Defense Advisory Committee on Military Personnel Testing (DACMPT) will take place.

DATES: Day 1—Open to the public Wednesday, June 12, 2024 from 8:30 a.m. to 5:30 p.m., Pacific Time. Day 2—Open to the public Thursday, June 13, 2024, from 8:30 a.m. to 1:15 p.m., Pacific Time.

ADDRESSES: Venue to-be-determined (TBD). Meeting details will be posted on: *https://dacmpt.com.*

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO), Dr. Sofiya Velgach, (703) 697–9271 (Voice), 703 614–9272 (Facsimile), *osd.pentagon.ousd-p-r.mbx.dacmpt@mail.mil* (Email). Mailing address is Designated Federal Officer, Accession Policy, Office of the Under Secretary of Defense for Personnel and Readiness, Room 3D1066, The Pentagon, Washington, DC 20301–4000. The most up-to-date changes to the meeting can be found on the website: *https://dacmpt.com.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''); 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''); and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to provide an overview of the accession testing program, review progress on the test development efforts, provide an update on the calculator study, and gather advice on current testing capabilities. Additional information can be found at *https://dacmpt.com.*

Agenda

Day 1, Wednesday, June 12, 2024 (Pacific Time)

8:30 a.m.–8:45 a.m.: Welcome and Opening Remarks—Dr. Sofiya Velgach, OASD(M&RA)/AP
8:45 a.m.–9:15 a.m.: Accession Policy Brief—Dr. Katherine Helland, OASD(M&RA)/AP
9:15 a.m.–10:00 a.m.: R&D Milestones Brief—Dr. Mary Pommerich, OPA/DTAC
10:00 a.m.–10:15 a.m.: *Break*
10:15 a.m.–11:15 a.m.: Next Generation Testing—Dr. Kimberly Adams, HumRRO
  a. Test Overviews
  b. How Pieces Fit Together
  c. Roadmap Efforts
11:15 a.m.–12:15 p.m.: Form Development Methodology—Dr. Glen Heinrich-Wallace, Dr. Ted Diaz (HumRRO)
  a. Calibration Sample Size Study
  b. Use of Machine Learning and Natural Language Processing Method
12:15 p.m.–1:45 p.m.: *Lunch*
1:45 p.m.–2:45 p.m.: Form Equating Simulation Study—Dr. Jeff Dahlke (HumRRO)
2:45 p.m.–3:45 p.m.: Calculator Analyses Efforts—Dr. Andrea Sinclair, HumRRO
3:45 p.m.–4:00 p.m.: *Break*
4:00 p.m.–4:30 p.m.: Complex Reasoning Update—Dr. Kate Klein (HumRRO)
4:30 p.m.–5:00 p.m.: Computational Thinking Update—Dr. Kimberly Adams, Dr. Scott Oppler (HumRRO)
5:00 p.m.–5:15 p.m.: *Public Comments*

Day 2, Thursday, June 13, 2024 (Pacific Time)

8:30 a.m.–9:30 a.m.: Non-Cognitive Updates
  a. Joint—Service TAPAS Background—Dr. Dan Putka, Dr. Tim McGonigle, HumRRO
  i. Identification of Phase 0 Composites
  ii. Development of Phase 1 Composites
  iii. JS TAPAS Instrument Planning and Composite Refinement
  b. Best Practices Project Team—MC Dr. Brenda Ellis, HumRRO
9:30 a.m.–10:30 a.m.: Norming Efforts—Dr. Rod McCloy (HumRRO)
10:30 a.m.–10:45 a.m.: *Break*
10:45 a.m.–11:30 a.m.: ASVAB CEP Dr. Irina Rader, Ms. Temeka Franklin, OPA/DTAC
11:30 a.m.–11:45 a.m.: Legislation/Policy Review Dr. Sofiya Velgach, OASD(M&RA)/AP
11:45 a.m.–12:00 p.m.: Resource Overview—Dr. Mary Pommerich, OPA/DTAC
  a. Systems
  b. Staffing
  c. Funding
12:00 p.m.–12:30 p.m.: Prioritization of Recommendations—Dr. Sofiya Velgach, OASD(M&RA)/AP
12:30 p.m.–12:45 p.m.: Future Topics Dr. Mary Pommerich, OPA/DTAC
12:45 p.m.–1:00 p.m.: *Public Comments*
1:00 p.m.–1:15 p.m.: Closing Comments—Dr. Nancy Tippins, Chair
1:15 p.m.–3:00 p.m.: *Working Lunch (Administrative Items)*

Abbreviations Key

ASVAB—Armed Services Vocational Aptitude Battery
ASVAB CEP—ASVAB Career Exploration Program, student testing program provided at no cost to high schools nation-wide to help students develop career exploration skills and used by recruiters to identify potential applicants for enlistment
HumRRO—Human Resources Research Organization
JS—Joint Service
MC—Military Compatibility
OASD(M&RA)/AP—Office of the Assistant Secretary of Defense for Manpower and Reserve Affairs/Accession Policy
OPA/DTAC—Office of People Analytics/Defense Testing and Assessment Center
TAPAS—Tailored Adaptive Personality Assessment System

Latest version of the agenda will be posted on *https://dacmpt.com.*

Meeting Accessibility: Pursuant to 5 U.S.C. 1009(a)(1) and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating availability is based on first-come, first-served basis. All members of the public who wish to attend the public meeting must contact the DFO no later than 12:00 p.m. on Monday, June 3, 2024, as listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and 5 U.S.C. 1009(a)(3), interested persons may submit written statements to the DACMPT at any time about its approved agenda or at any time on the DACMPT's mission. Written statements should be submitted to the DACMPT's DFO at the address or facsimile number listed in the **FOR FURTHER INFORMATION CONTACT** section. If statements pertain to a specific topic being discussed at the planned meeting, then these statements must be submitted no later than five (5) business days prior to the meeting in question. Written statements received after this date may not be provided to, or not considered by the DACMPT until its next meeting. The DFO will review all timely submitted written statements and provide copies to all the DACMPT members before the meeting that is the subject of this notice. Please note that since the DACMPT operates under the provisions of the FACA, all submitted comments and public presentations will be treated as public documents and will be made available for public inspection. Opportunity for public comments will be provided at the end of each day. Public comments will be limited to 5 minutes per person, as time allows.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09574 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Proposals by Non-Federal Interests for Inclusion in the Annual Report to Congress on Future Water Resources Development

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The Assistant Secretary of the Army for Civil Works (ASA(CW)) is soliciting proposals for inclusion in the 2025 Annual Report to Congress on Future Water Resources Development (Annual Report). The Annual Report includes proposals submitted by non-federal interests for new feasibility studies, proposed modifications to authorized water resources development projects or feasibility studies, and proposed modifications to environmental infrastructure program authorities. The Annual Report is authorized under section 7001 of the Water Resources Reform and Development Act (WRRDA) of 2014, as amended.

DATES: Proposals must be submitted by August 30, 2024.

ADDRESSES: Submit proposals by emailing the completed proposal form

to *WRRDA7001Proposal@usace.army.mil.* If a different method of submission is required, use the further information below to arrange an alternative submission process.

FOR FURTHER INFORMATION CONTACT: For further information about the Annual Report, visit the U.S. Army Corps of Engineers (USACE) Headquarters website (*https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/WRRDA-7001-Proposals/*), email *WRRDA7001Proposal@usace.army.mil,* or call Michele Gomez, Planning and Policy Division, Headquarters, USACE, Washington, DC at 202–761–7193.

SUPPLEMENTARY INFORMATION:

A. Background on the Annual Report

The Annual Report to Congress on Future Water Resources Development, prepared pursuant to section 7001 of WRRDA 2014, as amended (33 U.S.C. 2282d), provides an opportunity for communities to inform Congress about their interest in a new congressional authorization—or modifying an existing authorization—for specifically authorized Civil Works water resources studies, projects, and environmental infrastructure programs. The Annual Report provides Congress with a list of potential studies and projects to newly authorize and a list of existing study, project, and environmental infrastructure program authorities to modify. Congress generally authorizes new USACE studies, projects, and environmental infrastructure programs in an omnibus authorization bill, typically called the Water Resources Development Act (WRDA).

If a proposal from a non-federal interest for a new study authorization is included in the Annual Report, it is anticipated that authorization would be for the study, not for construction. To begin a water resources feasibility study, USACE must have sufficient study authority, and funds must be appropriated and made available for the ederal cost share of the feasibility study. A primary outcome of a USACE water resources feasibility study is a recommendation for Congressional authorization to construct a water resources project. For USACE to proceed to construction, the project must be authorized for construction by Congress, and funds must be appropriated and made available for project construction. An overview of USACE Civil Works water resources study and project processes is found in the document entitled ''Partnering with the U.S. Army Corps of Engineers: A Guide for Communities, Local Governments, States, Tribes, and Non-Governmental Organizations,'' which is available online at *https://planning.erdc.dren.mil/toolbox/library/IWRServer/2019-R-02.pdf.*

B. Sources of More Information

1. USACE will host two public virtual information sessions about the Annual Report and the proposal submission and evaluation process for the 2025 Annual Report on June 25, 2024, and August 8, 2024.The Headquarters website (*https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/WRRDA-7001-Proposals/*) contains additional information and frequently asked questions about the Annual Report.

2. The local USACE district office will assist in researching and identifying existing Congressional authorities for Civil Works water resources feasibility studies, projects, and environmental infrastructure programs. Websites for all USACE district offices are available online at: *https://www.usace.army.mil/Contact/Unit-websites/.*

C. Definition of Non-Federal Interest

Proposals for the Annual Report are submitted by non-federal interests, and each feasibility study or project is conducted in partnership with a non-federal interest. For the purposes of the Annual Report, the term ''non-federal interest'' is defined in section 221(b) of the Flood Control Act of 1970 (Pub. L. 91–611), as amended (42 U.S.C. 1962–5b(b)). The term ''non-federal interest'' means (1) a legally constituted public body (including an Indian Tribe and a Tribal organization (as those terms are defined in section 5304 of title 25)); or (2) a nonprofit entity with the consent of the affected local government, that has full authority and capability to perform the terms of its agreement and to pay damages, if necessary, in the event of failure to perform.

D. Proposal Form

The information for proposals from a non-federal interest is normally entered into a fillable PDF form which can be found at the HQ Annual Report website and submitted by email to *WRRDA7001Proposal@usace.army.mil.* If a different method of submission is needed, use the contact information in the **FOR FURTHER INFORMATION CONTACT** section of this Notice to arrange an alternative submission process. Proposals must be submitted by August 30, 2024.

The fillable PDF proposal form requests the following information:

1. Contact information for the individual/agency submitting the proposal: name, phone number, email.

2. Proposal Name.

3. Project Location (State(s)/Territory).

4. Study or project area map; you'll have the option to upload a map of the study/project area (preferred format is an 8.5″ x 11″ PDF).

5. Specific project purpose(s) of the proposed study or modification (USACE mission areas).

6. Project description: demonstrate the proposal is related to USACE missions and authorities and why additional or new authorization is needed.

7. State if this proposal is for a new feasibility study, a modification to a USACE water resources development feasibility study authority, a modification to a USACE water resources project authority, or a modification to a USACE environmental infrastructure program authority.

8. If the proposal is for a modification to an existing authority, provide the name of the authorized study, project, or environmental infrastructure program. Cite the authority (*e.g.,* section of WRDA) if possible.

9. If the proposal is for a modification to an environmental infrastructure program authority, provide a brief description of the assistance provided to date and total federal cost of assistance provided to date.

10. Provide an estimate, to the extent practicable, of the total cost, and the federal and non-federal share of those costs, of the proposed study and, separately, an estimate of the cost of construction or modification.

11. Describe, to the extent applicable and practicable, an estimate of the anticipated monetary and non-monetary benefits of the proposal regarding benefits to the protection of human life and property and improvement to transportation, the national, regional, or local economy, the environment, or the national security interests of the United States.

12. *Optional:* State whether the proposal is expected to benefit disadvantaged communities, including a description of the disadvantaged community(ies) and the potential benefits which may accrue as a result of the proposal. See the Council for Environmental Quality (CEQ) website for information on (1) categories of burden at the following location (*https://screeningtool.geoplatform.gov/en/methodology*), (2) an economic justice screening tool to help identify disadvantaged communities (*https://screeningtool.geoplatform.gov.*)

13. The name of the non-federal interest planning to act as the sponsor, or all non-federal interests in the case of a modification to an environmental infrastructure program authority,

including any non-federal interest that has contributed to or is expected to contribute toward the non-federal share of the proposed feasibility study or modification.

14. A statement of support from each associated non-federal interest. Optional: attach letter(s) of support from interested stakeholders. Letters may be addressed generically to the U.S. Army Corps of Engineers, the local Corps District office, or the Assistant Secretary of the Army of Civil Works office.

15. State if the non-federal interest has the financial ability to provide for the required cost share.

16. State if there is local support for the proposal and describe the local support.

A complete list of information requested on the proposal form is available on the USACE Headquarters Annual Report web page: *https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/WRRDA-7001-Proposals/.*

The information provided in a proposal will be posted to the Headquarters public website for the Annual Report. Therefore, any information that is Confidential Business Information, information that should not be disclosed because of statutory restrictions, or any other information that a non-federal interest would not want to appear publicly should not be included in the proposal.

E. Evaluation Criteria

All proposals submitted within the time frame set forth in this notice will be considered for inclusion in the 2025 Annual Report to Congress on Future Water Resources Development. To be included in the Annual Report table, the proposals must meet all the following five criteria established by Congress:

1. The proposal is related to USACE missions and authorities. The proposal must involve a proposed or existing USACE water resources project or effort where the primary purpose is flood and/or coastal storm damage reduction, commercial navigation, aquatic ecosystem restoration, or municipal or agricultural water supply. Proposals for recreation or hydropower are eligible for inclusion if undertaken in conjunction with one of the primary purposes listed in this paragraph.

2. The proposal requires specific Congressional authorization, including by an Act of Congress.

3. The proposal has not been previously authorized by Congress.

4. The proposal has not been included in the Annual Report table of any previous Annual Report to Congress on Future Water Resources Development.

5. The proposal, if authorized, could be carried out by USACE.

The purpose of the five criteria is, primarily, to determine if a proposal will require Congressional authorization for USACE to undertake the proposed water resources study or project with the non-federal interest.

Proposals for modifications to environmental infrastructure authorities are an exception to the criteria. To be included in the table within the Annual Report, the proposal must be a modification to a project that was authorized pursuant to section 219 of WRDA 1992, as amended, or must identify a programmatic modification to an environmental infrastructure assistance program, and it has not been included in any previous annual report.

Additional information and frequently asked questions on the five criteria are available on the USACE Headquarters Annual Report web page: *https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/WRRDA-7001-Proposals/.*

F. Contents of the Annual Report

The Annual Report will be transmitted to Congress by the ASA(CW) and posted to the USACE Headquarters website at *https://www.usace.army.mil/Missions/Civil-Works/Project-Planning/WRRDA-7001-Proposals/.*

1. The Annual Report will include a certification by the ASA(CW) stating that each proposal included in the Annual Report meets the five criteria established by Congress or the requirements for proposed modifications to environmental infrastructure program authorities.

2. Signed Chief's Reports recommending authorization of a water resources project will be included in the Annual Report table by the ASA(CW); these proposals should not be submitted in response to this notice.

3. Section 902 of WRDA 1986, as amended, (33 U.S.C. 2280) establishes a maximum authorized cost for water resources projects (also known as the 902 limit). A post authorization change report is required to be completed to support potential modifications to the project authority, including updates to authorized project costs. Completed post authorization change reports recommending modifications to the authorization of a water resources project will be included in the Annual Report table by the ASA(CW); these proposals should not be submitted in response to this notice.

4. Proposals that do not meet all five criteria established by Congress or the requirements for proposed modifications to environmental infrastructure program authorities will be included in an appendix table included in the Annual Report to Congress on Future Water Resources Development. Proposals in the appendix table will include a description of why those proposals did not meet the criteria established by Congress.

Michael Connor,

Assistant Secretary of the Army (Civil Works).

[FR Doc. 2024–09576 Filed 5–1–24; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN–2024–HQ–0006]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Commander, Navy Installations Command (CNIC) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 1, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions

from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Commander, Navy Installations Command (CNIC), 716 Sicard Street SE, Suite 100, Washington DC, 20374–5140, ATTN: Mr. Horace Franklin, or call 901–307–6872.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Anchored4Life Evaluability Study Interviews; OMB Control Number 0703–AFLT.

Needs and Uses: DoD Child Youth Programs (CYPs) require the Anchored4Life program (A4L) to provide Transition and Resiliency training to U.S. Navy (USN), Air Force (USAF), Space Force (USSF), Army (USA), and Marine Corps (USMC) school-based elementary, middle and high schools, installation CYPs, and Geo-dispersed locations. Service Branch CYPs are required by title 10 U.S.C. 1785, ''Youth Sponsorship Program,'' and DoD Instruction 6060.04, ''Youth Services (YS) Policy,'' to provide School Liaison and Youth Sponsorship programs. Service Branches use CYP Education Services (CYES) to execute this requirement using School Liaisons (SL), School Based Programs (SBP) and Youth Programs (YP). Execution includes providing resiliency and transition training and support, as well as system navigation assistance to parents of military associated children. A4L is an essential element of the military CYPs, PreK–12 System Navigation, and youth sponsorship programs and shall be provided at military installations and be available to Geo-dispersed locations.

The USN, USAF, and USSF, through the Trevor Romain Contract HDQMWR–21–D–003, are requesting Office of Management and Budget (OMB) clearance for a qualitative study of the A4L program intended to support military-connected youth. Military-connected youth face unique challenges specific to their association with the military in addition to those that are similar to their civilian counterparts. There has been little research examining the implementation or effectiveness of programs and initiatives specifically available to support military-connected youth.

The purpose of this study is to investigate the implementation of A4L training to support military-connected youth (kindergarten through 12th grade), to review current research on K–12 military-connected youth, and evaluate A4L programming to determine effectiveness of transition, deployment support, resiliency impact on other key youth issues including bullying prevention and recovery from grief. The long-term goal is to foster life skills and resiliency in military-connected youth, of which about 45% enter Military Service as adults.

To answer these evaluative questions, semi-structured interview questions will address awareness, implementation, impact, barriers, improvement, and coordination between stakeholders related to A4L impact on military-connected youth who participate.

Affected Public: Individuals or households.

Annual Burden Hours: 232.

Number of Respondents: 576.

Responses per Respondent: 1.

Annual Responses: 576.

Average Burden per Response: 24.17 minutes.

Frequency: Once.

Dated: April 29, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–09557 Filed 5–1–24; 8:45 am]

BILLING CODE 6001–FR–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2020–0617; FRL–11648–01–OCSPP]

Agency Information Collection Activities; Proposed Renewal of an Existing ICR Collection and Request for Comment; Collection of Information for TSCA Mercury Inventory Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces the availability of and solicits public comment on the following Information Collection Request (ICR) that EPA is planning to submit to the Office of Management and Budget (OMB): ''Collection of Information for TSCA Mercury Inventory Reporting,'' identified by EPA ICR No. 2567.05 and OMB Control No. 2070–0207. This ICR represents a renewal of an existing ICR that is currently approved through February 28, 2025. Before submitting the ICR to OMB for review and approval under the PRA, EPA is soliciting comments on specific aspects of the information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before July 1, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0617, through the Federal eRulemaking Portal at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Katherine Sleasman, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–1206; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of

specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Collection of Information for TSCA Mercury Inventory Reporting.

EPA ICR No.: 2567.05.

OMB Control No.: 2070–0207.

ICR status: This ICR is currently approved through February 28, 2025. Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: As directed under TSCA, EPA is required to assist in the preparation and publication in the **Federal Register** of an ''inventory of mercury supply, use, and trade in the United States'' (15 U.S.C. 2607(b)(10)(B) and (D)). Based on the inventory of information collected through this ICR, the Agency is directed to ''identify any manufacturing processes or products that intentionally add mercury'' and ''recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use'' (15 U.S.C. 2607(b)(10)(C)).

The primary purpose of this ICR is to support the development of that inventory. In turn, the inventory will help the Agency identify uses of mercury and recommend means to achieve further reductions of such uses in commerce. In addition, the Agency seeks to obtain the information necessary to achieve its goal to further reduce the use of mercury in products and certain manufacturing processes in order to prevent future releases to the environment, as well as assist the United States in reporting implementation under the Minamata Convention. EPA seeks to enhance its current information on how much mercury is used, in which products and manufacturing processes, and whether certain products are manufactured domestically, imported, or exported.

Reporting is required from any person who manufactures (including imports) mercury or mercury-added products, as well as any person who otherwise intentionally uses mercury in a manufacturing process under TSCA section 8(b). The Agency promulgated reporting requirements at 40 CFR part 713. To avoid duplication, EPA coordinated the reporting with the Interstate Mercury Education and Reduction Clearinghouse (IMERC).

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 25 hours per respondent annually or a total of 75 hours per respondent over the three-year life cycle of the ICR. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Forms: 9600–024.

Respondents/affected entities: Entities potentially affected are those that manufacture (including import) mercury, manufacture (including import) mercury containing products, and those who intentionally use mercury in a manufacturing process.

Respondent's obligation to respond: Mandatory, per 40 CFR 713.

Frequency of response: Triennial.

Total estimated number of potential respondents: 105.

Total estimated average number of responses for each respondent: 1.

Total estimated annual respondent burden hours: 2573 hours.

Total estimated annual respondent costs: $223,592, which includes $0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 14,775 hours in the total estimated industry respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects a change in EPA's method of estimating the number of expected reports. In 2021, EPA amended the original final rule to effectuate the vacatur ordered by the Second Circuit Court. In this ICR, with data available from the Mercury Inventory and with no new changes to the rule itself, this ICR utilizes data from the Reporting Year 2021 of the Mercury Inventory. In the RY 2021, there were 105 submissions (the previous ICR used an estimate of 252). This ICR assumes each respondent completes the entire form. Wages were also updated to 2022 dollars. These changes represent adjustments.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 26, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2024–09527 Filed 5–1–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 217231]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written PRA comments should be submitted on or before July 1, 2024.

If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION: The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

OMB Control Number: 3060–xxxx.

Title: Section 9.10(s), Location-Based Routing for Wireless 911 Calls.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 59 respondents; 59 responses.

Estimated Time per Response: 40 hours.

Frequency of Response: One-time and on occasion reporting requirement.

Obligation to Respond: Mandatory. Statutory authority for this collection is contained in sections 1, 2, 4(i), 4(j), 4(o), 251(e), 303(b), 303(g), 303(r), 316, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 154(o), 251(e), 303(b), 303(g), 303(r), 316, 403, and section 4 of the Wireless Communications and Public Safety Act of 1999, Public Law 106–81, sections 101 and 201 of the New and Emerging Technologies 911 Improvement Act of 2008, Public Law 110–283, and section 106 of the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, as amended 47 U.S.C. 615a, 615a–1, 615b, 615c.

Total Annual Burden: 2,360 hours.

Total Annual Cost: No Cost.

Needs and Uses: Technical limitations of legacy Enhanced 911 (E911) routing can result in a Commercial Mobile Radio Service (CMRS) provider routing a wireless 911 call to a Public Safety Answering Point (PSAP) other than the one designated by the relevant state or local 911 authority to receive calls from the actual location of the caller. To improve emergency response times, the Commission adopted rules and procedures to require CMRS providers to implement location-based routing (LBR) for wireless 911 voice calls and real-time text (RTT) communications to 911 nationwide. With location-based routing as implemented under the Commission's rules, CMRS providers will use precise location information to route wireless 911 voice calls and RTT communications to 911 to the appropriate public safety answering point. To facilitate the implementation of location-based routing for wireless 911 voice calls and RTT communications to 911, and to monitor compliance, promote transparency, and ensure accountability, the Commission adopted certain information collection requirements.

Certification and reporting. The Commission will use the information collected pursuant to section 9.10(s)(4) that is submitted by the CMRS providers in their compliance certifications, including technologies and methodologies used, and live call data reports to assess and monitor the implementation of LBR for wireless 911 voice calls and RTT communications to 911 call centers nationwide. Also, the Commission would use the data generated by the information collections to analyze the effectiveness of the LBR implementation at the benchmark dates set forth in the rules. In addition, it is imperative that CMRS providers ensure the privacy and security of location-based routing information.

Section 9.10(s)(4) requires that within 60 days after each benchmark specified in paragraphs (s)(1)(i), (ii), and (2) of section 9.10 of the rules, CMRS providers must comply with the following certification and reporting requirements.

Under section 9.10(s)(4)(i)(A), CMRS providers must certify that they are in compliance with the requirements specified in paragraphs (s)(1)(i), (ii), and (2) of this section applicable to them.

Under section 9.10(s)(4)(i)(B), CMRS providers must identify specific network architecture, systems, and procedures used to comply with paragraphs (s)(1)(i), (ii), and (2) of this section, including the extent to which the CMRS provider validates location information for routing purposes and the validation practices used in connection with this information.

Under section 9.10(s)(4)(i)(C), CMRS providers must certify that neither they nor any third party they rely on to obtain location information or associated data used for compliance with paragraphs (s)(1)(i), (ii), or (2) of this section will use such location information or associated data for any non-911 purpose, except with prior express consent or as otherwise required by law. The certification must state that the CMRS provider and any third parties it relies on to obtain location information or associated data used for compliance with paragraphs (s)(1)(i), (ii), or (2) of this section have implemented measures sufficient to safeguard the privacy and security of such location information or associated data.

Under section 9.10(s)(4)(ii)(A), CMRS providers must collect and report aggregate data on the routing technologies used for all live wireless 911 voice calls in the locations specified for live 911 call location data in paragraph (i)(3)(ii) of this section for a thirty-day period which begins on the compliance date(s) specified in paragraphs (s)(1)(i) and (ii) of this section. CMRS providers must retain live wireless 911 voice call data gathered pursuant to this section for a period of 2 years. CMRS providers must collect and report the following data, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section.

Under section 9.10(s)(4)(ii)(A)(*1*), CMRS providers must collect and report the data, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section, for live wireless 911 voice calls routed with location-based routing using location information that meets the timeliness and accuracy thresholds defined in paragraph (s)(3)(i)(A) and (B) of this section.

Under section 9.10(s)(4)(ii)(A)(*2*), CMRS providers must collect and report the data, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section, for live wireless 911 voice calls routed with location-based routing using location information that does not meet the timeliness or accuracy thresholds defined in paragraph (s)(3)(i)(A) and (B) of this section.

Under section 9.10(s)(4)(ii)(A)(*3*), CMRS providers must collect and report the data, expressed as both a number and percentage of the total number of live wireless 911 voice calls for which data is collected pursuant to this section, for live wireless 911 voice calls routed using tower-based routing.

Modification of deadlines by agreement. To monitor compliance dates agreed to between CMRS providers and PSAPs that are different from the compliance dates established

by the new rules, section 9.10(s)(5) establishes notification requirements for CMRS providers related to any modification of deadlines between the PSAPs and CMRS providers by mutual agreement. Nothing in this section of the rules shall prevent PSAPs and CMRS providers from establishing, by mutual consent, deadlines different from those established for CMRS provider compliance in paragraphs (s)(1)(i), (ii), and (2) of this section. The CMRS provider must notify the Commission of the dates and terms of the alternate time frame within 30 days of the parties' agreement or by June 12, 2024, whichever is later. The CMRS provider must subsequently notify the Commission of the actual date by which it comes into compliance with the location-based routing requirements in paragraphs (s)(1)(i), (ii), or (2) of section 9.10 within 30 days of that date or by June 12, 2024, whichever is later. The CMRS providers must file any such notifications pursuant to this paragraph (s)(5) in PS Docket No. 18–64.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–09480 Filed 5–1–24; 8:45 am]

BILLING CODE 6712–01–P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Public Financial Disclosure Extension Request

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice and request for comments.

SUMMARY: After this second round notice and public comment period, the U.S. Office of Government Ethics (OGE) plans to submit a new module allowing filers to request an extension of the time available to file a public financial disclosure report within its *Integrity* electronic filing system. This notice announces that OGE intends to submit this collection to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act.

DATES: Consideration will be given to all written comments received by June 3, 2024 .

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Jennifer Matis at the U.S. Office of Government Ethics; telephone: 202–482–9216; TTY: 800–877–8339; Email: *jmatis@oge.gov*.

SUPPLEMENTARY INFORMATION:

Title: Electronic Public Financial Disclosure Extension Request.

Abstract: The *Integrity* Public Financial Disclosure Extension Request will be a module within OGE's *Integrity* electronic filing application. Certain officers and high-level employees in the executive branch are required to file public financial disclosure reports via the OGE Form 278e and OGE Form 278–T for the purpose of conflict of interest review and public disclosure. The form is also completed by individuals who are nominated by the President for high-level executive branch positions requiring Senate confirmation and individuals entering into and departing from other public reporting positions in the executive branch.

In 2014, OGE sought and received approval to incorporate the OGE Form 278e into its *Integrity* electronic filing application. *Integrity* has been in use since January 1, 2015, and most executive branch public financial disclosure filers now use *Integrity* to file the OGE Form 278e and OGE Form 278–T. Although *Integrity* is primarily used by current executive branch federal employees, it is also used to file termination reports by certain filers who have recently left government service.

The proposed module within *Integrity* will allow filers to easily request an extension of time to file their report. The module can be ''turned on'' by the filer's reporting agency, or the agency may choose not to use it. Requests for extensions are currently made by calling or emailing the filer's agency ethics official and require that the filer provide a reason for requesting an extension. The ethics official can then manually enter the number of days granted into *Integrity* and those days will be displayed on the cover page of the printed report, which is made public in accordance with 5 U.S.C. 13107. If the extension was granted because the filer is in a combat zone, the reason for the extension is also noted on the report. Once the new feature is deployed and an agency chooses to enable the feature, their filers will request an extension through the *Integrity* module. The electronic extension request will then be presented within the *Integrity* application to the appropriate ethics official at the employing agency. If the ethics official grants the request, the required information will automatically appear on the filer's report as generated by the *Integrity* application.

OGE believes that many agencies will avail themselves of the option to use the new module. For those that do, automating this process will make it easier for both the filer and the agency ethics officials and will reduce the chance that required information will be omitted from the filer's report. The development of this feature has been ranked a high priority by the *Integrity* Advisory Council (IAC), which is comprised of a diverse group of agencies that have at least 90% of their financial disclosure filers utilizing the *Integrity* application. The IAC was established to advise OGE on proposed enhancements, improvements, and support services.

A **Federal Register** Notice with a 60-day comment period soliciting comments on this information collection was published on January 24, 2024 (89 FR 4609). OGE did not receive any comments in response.

OMB Control Number: To Be Determined.

Type of Information Collection: New collection.

Type of Review Request: Regular.

Affected Public: Private citizens who file termination reports from such positions after their government service ends.

Estimated Annual Number of Respondents: 511.

Estimated Time per Response: 2 minutes.

Estimated Total Annual Burden: 17 hours.

Request for Comments: Public comment is invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for, and may be included with, the OGE request for OMB approval under the Paperwork Reduction Act. The comments will also become a matter of public record.

Dated: April 8, 2024.

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2024–09478 Filed 5–1–24; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records Notice

AGENCY: Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice of two new systems of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the U.S. Department of Health and Human Services (HHS) is establishing two new systems of records that will be maintained by the Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP): System No. 09–80–0391, Anti-Trafficking Information Management System (ATIMS) Records; and System No. 09–80–0392, National Human Trafficking Training and Technical Assistance Center (NHTTAC) Participant Records.

DATES: In accordance with 5 U.S.C 552a(e)(4) and (11), this notice of two new systems of records is effective May 2, 2024, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by June 3, 2024.

ADDRESSES: The public should address written comments by mail to: Anita Alford, Senior Official for Privacy, Administration for Children and Families, 330 C Street SW, Washington, DC 20201; or by email to: *anita.alford@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: General questions about the systems of records may be submitted to Beth Kramer, HHS Privacy Act Officer, FOIA/Privacy Act Division, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, by mail at 200 Independence Ave. SW—Suite 729H, Washington, DC 20201, or by telephone at (202) 690–6941, or by email at *beth.kramer@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on OTIP Functions

On June 10, 2015, the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) established the Office on Trafficking in Persons (OTIP) and delegated to OTIP the authority to administer human trafficking programs formerly administered by ACF's Office of Refugee Resettlement (ORR). In addition to administering human trafficking programs, OTIP provides letters of Certification and Eligibility to foreign national victims of severe forms of trafficking in persons under the authority of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7105(b)(1), hereafter abbreviated ''TVPA''), to enable the victims to apply for federally-funded benefits and services to the same extent as refugees. Under the TVPA, OTIP is authorized to collect data and evaluate the effectiveness and efficiency of programs designed to serve victims of severe forms of trafficking in persons (see 22 U.S.C. 7103(d), 7104(b), 7105(b), and 7105(f)). Through participation on the President's Interagency Task Force to Monitor and Combat Trafficking (PITF), OTIP is authorized to conduct research on the causes, effectiveness, and interrelationship of human trafficking and global health risks while identifying an effective mechanism for quantifying the number of victims of trafficking on a national, regional, and international basis. OTIP authorizations include efforts to:

1. Measure and evaluate progress of the United States in the areas of prevention, protection, and assistance to victims of trafficking;

2. Expand interagency procedures to collect and organize data, including significant research and resource information on domestic and international trafficking with respect to the confidentiality of victims of trafficking; and

3. Engage in consultation and advocacy with government and nongovernmental organizations to advance the purposes of the PITF.

OTIP has determined that its performance of these functions requires maintenance of two new functionally different sets of records that will be subject to the Privacy Act (*i.e.,* records about individuals, retrieved by personal identifier), described in A and B, below. Both sets of records are functionally different from the OTIP consultant records covered in existing HHS departmentwide System of Records Notice (SORN) 09–90–1601, Outside Experts Recruited for Non-FACA Activities.

A. Records To Be Covered in New SORN 09–80–0391, Anti-Trafficking Information Management System (ATIMS) Records

SORN 09–80–0391 will cover case files that OTIP maintains about individuals who have or may have been subjected to a severe form of trafficking in persons in accordance with the TVPA. Currently, there are two main file types, briefly described below.

- *Case Files Associated with Requests for Assistance for Foreign National Child Victims of Human Trafficking*

The TVPA requires federal, state, and local officials to notify HHS not later than 24 hours after discovering that a foreign national minor may be a victim of trafficking (see 22 U.S.C. 7105(b)). OTIP developed a Request for Assistance (RFA) form for requesters (*i.e.,* assistance requesters) to use to notify HHS of trafficking concerns for foreign national minors (non-U.S. citizens or non-lawful permanent residents under the age of 18) who are currently in the United States and to request assistance on behalf of foreign national minors. Use of this form, or the completion of any section of this form, is optional. When an RFA is received, OTIP creates a case for the individual seeking assistance in an online case management system. OTIP uses case files, which contain information collected through the RFA process, to determine a child's eligibility for interim and long-term assistance (see 22 U.S.C. 7105(b)(1)(G)). If there is sufficient information during the RFA process to indicate that the child was subjected to forced labor and/or commercial sex (*i.e.,* experienced a severe form of trafficking in persons), OTIP will issue an Eligibility Letter, making the child eligible to apply for benefits and services to the same extent as a refugee. If there is sufficient information during the RFA process to indicate that the child may have been subjected to a severe form of trafficking in persons, OTIP will issue an Interim Assistance Letter, making the child eligible to apply for benefits and services to the same extent as a refugee for 90 days, or up to 120 days if extended. During the interim assistance period, OTIP will seek consultation from the U.S. Departments of Justice (DOJ) and Homeland Security (DHS), other government agencies, and nongovernmental organizations (NGOs) before issuing an Eligibility Letter or a Denial Letter. If the information OTIP receives during the RFA process does not indicate that the child may have been subjected to a severe form of trafficking in persons, OTIP will issue a Denial Letter to the child. OTIP will include instructions with the Denial Letter on how to request reconsideration and how to resubmit the child's case, if applicable.

- *Case Files Associated with Requests for HHS Certification of Foreign National Adult Victims of Human Trafficking*

OTIP provides letters of Certification to foreign national adult victims of severe forms of human trafficking under the authority of the TVPA (see 22 U.S.C. 7105(b)(1)). OTIP developed a Request for HHS Certification (RFC) form for requesters (*i.e.,* assistance requesters) to use to provide the required information for foreign national adult victims to obtain a Certification Letter. When an RFC is received, OTIP creates a case for the individual seeking Certification in an online case management system. OTIP uses case files, which contain information collected through the RFC process, to issue a Certification Letter. Certification is required for foreign national adult trafficking victims in the United States to apply for federally-funded benefits and services. Individuals can only receive an HHS Certification Letter if they have received Continued Presence, T–1 Nonimmigrant Status, or a Bona Fide T–1 Visa from the Department of Homeland Security (DHS) that has not been rescinded or denied. These immigration documents may be received and stewarded by OTIP as part of the process to issue a Certification Letter to eligible recipients.

The Privacy Act applies, in its entirety, only to U.S. citizens and lawful permanent residents. The Judicial Redress Act of 2015 (JRA), 5 U.S.C. 552a note, extends the right to pursue certain civil remedies in the Privacy Act (redress rights) to citizens of designated countries. While the above-described files may be about foreign nationals from *any* country, only foreign nationals who are from countries designated in accordance with the JRA have statutory rights under the Privacy Act, which are limited to redress rights.

B. Records To Be Covered in New SORN 09–80–0392, National Human Trafficking Training and Technical Assistance Center (NHTTAC) Participant Records

OTIP established the National Human Trafficking Training and Technical Assistance Center (NHTTAC) in 2016, pursuant to authority in the TVPA, to build the capacity of health and human services professionals and help prevent, identify, and respond to trafficking. OTIP implements the requirements of the Stop, Observe, Ask, and Respond to Health and Wellness Act of 2018 (42 U.S.C. 300d–54) through NHTTAC. NHTTAC works to further the agency's mission by increasing access to user-friendly, efficient, and cost-effective training and technical assistance resources for individuals, organizations, and communities on trafficking-related topics.

SORN 09–80–0392 will cover the following two types of records maintained by NHTTAC in participant files which are retrieved by the participant's name or other personal identifier:

- Records of feedback the individual provides to NHTTAC evaluating NHTTAC training and technical assistance (T/TA) programs and events in which the individual participated, which NHTTAC uses to address or clarify questions or issues raised by the participant; and
- Information about the individual's participation in SOAR *Online* trainings, which is used to issue Continuing Education/Continuing Medical Education (CE/CME) credits earned by participants.

A report on the two new systems of records was sent to OMB and Congress in accordance with 5 U.S.C. 552a(r), by the HHS Senior Agency Official for Privacy (SAOP), or the SAOP's designee, in accordance with OMB Circular A–108, section 7.e.

Dated: April 25, 2024.

Beth Kramer,

HHS Privacy Act Officer, FOIA-Privacy Act Division, Office of the Assistant Secretary for Public Affairs.

SYSTEM NAME AND NUMBER:

Anti-Trafficking Information Management System (ATIMS) Records, 09–80–0391.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of the agency component responsible for the system of records is: Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF) Immediate Office of the Assistant Secretary (IOAS), Department of Health and Human Services (HHS), Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201.

SYSTEM MANAGER(S) AND ADDRESS(ES):

The agency official who is responsible for the system of records is: System Owner, Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF) Immediate Office of the Assistant Secretary (IOAS), 330 C Street SW, Washington, DC 20201; Email: *EndTrafficking@acf.hhs.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 7105.

PURPOSE(S) OF THE SYSTEM:

The records in this system of records are used by OTIP to electronically process Requests for Assistance (RFA) and Requests for Certification (RFC), which are submitted to OTIP digitally via an online system that OTIP provides for this purpose and maintained in electronic case files. The records are accessed by OTIP personnel on a need-to-know basis for these purposes:

1. RFA case files contain information submitted by requesters. These files are used to make prompt determinations regarding a foreign national child's eligibility for assistance, to facilitate the required consultation process should the child receive interim assistance, to connect the child to trafficking-specific, comprehensive case management services through referral, and to assess and address potential child protection issues. OTIP issues an Interim Assistance or Eligibility Letter to a foreign national child in the United States, upon receipt of credible information which substantiates that the child may have been or was subjected to a severe form of trafficking in persons, to enable the minor to apply for federally-funded benefits and services to the same extent as a refugee. Such benefits and services include access to trafficking-specific case management services, medical services, food assistance, cash assistance, health insurance, education, and other needed services.

2. RFC case files contain information submitted by requesters. These files are used to issue a Certification Letter to a foreign national adult trafficking victim to enable the adult victim to apply for federally-funded benefits and services to the same extent as refugees. OTIP issues a Certification Letter to a foreign national adult in the United States who has experienced a severe form of trafficking after OTIP receives notice from the U.S. Department of Homeland Security (DHS) that a Continued Presence, or a T visa, has been granted or that a bona fide T visa application has not been denied with respect to that adult. Benefits and services include access to trafficking-specific case management services, medical services, food assistance, cash assistance, health insurance, education, and other needed services.

3. Records in both types of files may be used to inform HHS research and for quality assurance purposes directed at program improvement and policy development.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records are about the following categories of individuals:

- Foreign national minors identified as potential trafficking victims on RFA forms submitted to OTIP; and

• Foreign national adults identified as trafficking victims on RFC forms submitted to OTIP.

Note: Individuals who submit RFA and RFC forms to OTIP on behalf of trafficking victims or who serve as case management points of contact at other agencies, nongovernmental organizations (NGOs), and other entities that provide benefits and services to trafficking victims are not considered record subjects for purposes of this system of records, because all records involving them are about them in a representative capacity only.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of electronic case files associated with RFAs and RFCs, containing the information described below. The information technology system that OTIP uses to receive RFAs and RFCs and to maintain the case files allows for case file information to be collected through structured fields, open text fields, and document attachments.

• Case files associated with RFAs contain information that is pertinent to an eligibility determination and the case management needs of an individual child. An RFA case file includes: personal identifiers such as the child's name, date of birth, and Alien Registration Number; information about the child's experiences, including information about the child's background, adverse childhood experiences, and family history; information pertaining to emergency case management or child protection needs, and; information specific to the exploitation the child experienced, including the type of trafficking exploitation experienced, and the industry or venue where that exploitation took place. The case file also contains information about the assistance requester(s) who submitted the RFA on behalf of the child, including their name, phone number, and email address, to facilitate the required consultation process should the child receive interim assistance, to connect the child to trafficking-specific, comprehensive case management services through referral, and to assess and address potential child protection issues.

• Case files associated with RFCs contain information that is pertinent to issuing a Certification Letter to an adult who DHS has identified as having experienced a severe form of trafficking in persons and, to connect the adult to trafficking-specific, comprehensive case management services through referral. The case files include: personal identifiers, such as the adult trafficking victim's name, date of birth, and Alien Registration Number; information pertaining to emergency case management needs; information about the type of trafficking experienced (sex, labor, sex and labor); and related documentation from DHS (Continued Presence, T visa, bona fide T visa documentation and date of issuance). The case files also contain information about the assistance requester(s) who submitted the RFC on behalf of the adult trafficking victim, including their name, phone number, and email address to connect the adult to trafficking-specific, comprehensive case management services through referral, if requested.

RECORD SOURCE CATEGORIES:

Information in case files is provided directly by the trafficking victim or is provided by case managers, attorneys, law enforcement officers, child welfare workers, or other representatives assisting the victim.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974 at 5 U.S.C. 552a(b), under which HHS may disclose information from this system of records without the consent of the data subject. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible and appropriate. For example, information that a Violence Against Women Act (VAWA) funding recipient could not lawfully disclose under the confidentiality provision of that Act, 34 U.S.C. 12291(b)(2), would not be unlawful for HHS to disclose, because HHS is not a VAWA funding recipient so is not subject to that provision; however, it would be inappropriate for HHS to disclose, because HHS chooses to comply with that provision voluntarily.

1. *Disclosure to HHS Contractors, Grant Recipients, and Other Agents.* Information may be disclosed to contractors, consultants, grant recipients, and other agents engaged by HHS to assist in the fulfillment of an HHS function relating to the purposes of this system of records and who need to have access to the records in the performance of their duties or activities for HHS.

2. *Disclosures in Litigation and Other Proceedings.* Information may be disclosed to the Department of Justice (DOJ) or to a court or other adjudicatory body in litigation or other adjudicatory proceedings, when HHS or any of its components, or any employee of HHS in his or her official capacity, or any employee of HHS in her or her individual capacity where DOJ or HHS has agreed to represent the employee, or the United States Government, is a party to the proceedings or has an interest in the proceedings and, by careful review, HHS determines that the records are both relevant and necessary to the proceedings.

3. *Disclosure to Exchange Information With Other Government Agencies.* Information may be disclosed to the Department of Labor and other government agencies (including foreign, federal, state, Tribal, and local agencies) to exchange information with them for the purpose of preventing and responding to child and adult labor exploitation and trafficking.

4. *Disclosure to Service Provider.* Information may be disclosed to a provider of services to foreign national adults and children, including migrant and refugee youth, a foster care agency or national refugee resettlement agency, or to a local, county, or state institution (*e.g.,* state refugee coordinator, child welfare agency, court, or social service agency) for the purpose of providing trafficking-specific case management services to individuals covered by this system of records.

5. *Disclosure to an Attorney or Representative.* Information may be disclosed to an attorney or representative (as defined in 8 CFR 1.2) who is acting on behalf of an individual covered by this system of records in connection with any proceeding before the Department of Homeland Security or the Executive Office for Immigration Review, or under other circumstances when records are requested by counsel representing individuals covered by this system of records.

6. *Disclosure Incident to Requesting Information.* Information may be disclosed (to the extent necessary to identify the individual, inform the source of the purpose of the request, and identify the type of information requested), to any source from which additional information is requested when necessary to obtain information relevant to an agency decision concerning benefits.

7. *Disclosure to Congressional Office.* Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the written request of the individual.

8. *Disclosure in Connection with Settlement Discussions.* Information may be disclosed in connection with settlement discussions regarding claims by or against HHS, including public

filing with a court, to the extent that disclosure of the information is relevant and necessary to the discussions.

9. *Disclosure for Monitoring Waste, Fraud, or Abuse Purposes.* Information may be disclosed to another Federal agency or instrumentality of any governmental jurisdiction within or under the control of the United States (including the State or local governmental agency) that administers or has the authority to investigate potential fraud, waste, or abuse in federally-funded programs, when disclosure is deemed reasonably necessary by HHS to prevent, deter, discover, detect, investigate, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

10. *Disclosure in the Event of a Security Breach Experienced by HHS.* Information may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS' efforts to respond to the suspected or confirmed breach, or to prevent, minimize, or remedy such harm.

11. *Disclosure to Assist Another Agency Experiencing a Breach.* Information may be disclosed to another federal agency or federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are stored electronically, in a database which is backed-up on a daily basis.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Each individual who is identified in an RFA or RFC as a trafficking victim or potential victim is assigned a unique case identification number (*i.e.* HHS Tracking Number). OTIP (and assistance requesters who submit RFAs and RFCs to OTIP) retrieves records by the trafficking victim's name (first, middle, last), date of birth, and Alien Registration Number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

A disposition schedule is currently pending approval by the National Archives and Records Administration (NARA). When approved by NARA, it will provide for case file information gathered during the RFA and RFC processes, in identifiable form, to remain in HHS' custody for 15 years, or longer if needed for HHS' business use. Under a separate, NARA-approved disposition schedule, DAA–0292–2020–0001, the records that have met their retention period under the pending schedule will be accessioned (in identifiable form, in case needed for investigative purposes) to the National Archives of the United States for permanent retention.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards conform to the HHS Information Security and Privacy Program, *https://www.hhs.gov/ocio/securityprivacy/index.html.* Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS Information Systems Security and Privacy Policy (IS2P), all pertinent National Institutes of Standards and Technology (NIST) publications, and OMB Circular A–130 Managing Information as a Strategic Resource. Records will be protected from unauthorized access through appropriate administrative, technical, and physical safeguards under the supervision of the ACF Office of the Chief Information Security Officer (OCIO). The system leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRamp) requirements.

Administrative safeguards include requiring security and privacy training for Federal personnel and contractor staff and requiring Rules of Behavior (ROB) to be signed by database users. Technical controls include role-based access, user identification, passwords, firewall, and maintenance of intrusion detection functionality. Physical controls include the use of nondescript facilities to house the database and backup equipment, with security staff controlling both the perimeter and various ingress points within the buildings, video surveillance, intrusion detection systems, fire detection and suppression, uninterruptible power supply (UPS), and climate control. Additionally, all individuals accessing the buildings are required to use two-factor authentication a minimum of two times for entry, and any visitor or contractor must sign in and be escorted at all times by an authorized individual.

RECORD ACCESS PROCEDURES:

An assistance requester may check the status of an RFA or RFC the assistance requester submitted on behalf of a victim (subject individual) via the online verification page, *https://shepherd.otip.acf.hhs.gov/shepherdpublic/letterverification,* using the HHS Tracking Number and one of the following: victim's date of birth, last name, or benefits start date.

All other requests for information about a victim referred to OTIP through a RFA or RFC must be made in writing by the subject individual's legal representative on the law firm or legal agency's letterhead. The request must be sent to the email address (*EndTrafficking@acf.hhs.gov*) or mailing address specified in the ''System Manager(s)'' section of this SORN. The request letter must include: the name, alias, date of birth, nationality, and Alien Registration Number of the subject individual, the name of the requesting legal representative, and the reasons why the records are being requested. The following supporting documentation must also be submitted:

- A copy of the signed and executed *G–28, EOIR–27* or *EOIR–28.* These forms are not required for attorneys who work for, or volunteer pro bono services for, non-profit legal service providers funded by the VERA Institute of Justice for ORR's Division of Children's Services' legal access and outreach project
- An *Authorization for Release of Confidential Records* on the law firm/legal agency's letterhead stationery signed by the subject individual if the subject individual is 14 years of age or older and is not legally incompetent or by the subject individual' parent or legal guardian if the subject individual is under 14 years of age or is legally incompetent.
- The authorization must specify to whom the requested records should be released and the duration of the authorization.

So that OTIP may verify the identities of the subject individual and the subject individual's requesting legal representative (and, if applicable, the subject individual's parent or legal guardian), their signatures must be

notarized or the request must include, for each of them, a written, signed certification signed under penalty of perjury stating that he/she is the individual who he/she claims to be and that he/she understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. Evidence of any parent or guardian relationship must also be provided with the request, unless previously provided to OTIP.

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend records about them in this system of records must submit a written amendment request to the System Manager identified in the ''System Manager(s)'' section of this SORN, containing the same information required for an access request. The amendment request must include verification of identities in the same manner required for an access request; must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURE:

Individuals who wish to know if this system of records contains records about them must submit a written notification request to the System Manager identified in the ''System Manager(s)'' section of this SORN. The notification request must contain the same information required for an access request and must include verification of identities in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

SYSTEM NAME AND NUMBER:

National Human Trafficking Training and Technical Assistance Center (NHTTAC) Participant Records, 09–80–0392.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The address of the agency component responsible for the system of records is: Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF) Immediate Office of the Assistant Secretary (IOAS), Department of Health and Human Services (HHS), Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201.

SYSTEM MANAGER(S) AND ADDRESS(ES):

The agency official who is responsible for the system of records is: System Owner, Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF) Immediate Office of the Assistant Secretary (IOAS), 330 C Street SW, Washington, DC 20201; Email: *EndTrafficking@acf.hhs.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 7105, 42 U.S.C. 300d–54.

PURPOSE(S) OF THE SYSTEM:

OTIP established the National Human Trafficking Training and Technical Assistance Center (NHTTAC) to build the capacity of health and human services professionals and help prevent, identify, and respond to trafficking through training and technical assistance (T/TA). On OTIP's behalf, NHTTAC collects personally identifiable information (PII) about participants in NHTTAC's T/TA offerings to inform evaluation efforts, to assess customer satisfaction with T/TA offerings, and to issue Continuing Education/Continuing Medical Education (CE/CME) credits to eligible participants. Within NHTTAC, identifiable records about participants are retrieved by personal identifier and used by NHTTAC personnel on a need-to-know basis, for these purposes:

- To identify individuals who submit applications and their needs for specialized and/or short-term training and technical assistance from OTIP, including geographic locations where T/TA is requested and provided.
- To identify individuals who enroll in and complete the Stop. Observe. Act. Respond. (S.O.A.R) Health and Wellness online (SOAR *Online*) and in-person training program and receive CE/CME credits for their participation.
- To report the fulfillment of Continuing Education/Continuing Medical Education (CE/CME) credits to the appropriate accrediting bodies.

On a need-to-know basis, information from this system of records may be shared with relevant offices within HHS, including OTIP. OTIP and the following offices support NHTTAC activities, particularly through the SOAR Coordinating Group, and might receive participant contact information (*e.g.,* name, email address and/or phone number) once OTIP has approved the delivery T/TA services and for future T/TA planning purposes: Office of the Chief Information Officer (OCIO), Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT), Health Resources and Services Administration (HRSA) Office for Women's Health (OWH), Office of the Assistant Secretary for Health (OASH) Office on Women's Health (OWH), Center for Disease Prevention and Control (CDC) Division of Violence Prevention (DVP), and OASH Office of Regional Operations (ORO). The PII is provided through the NHTTAC interface, encrypted email message, or by phone.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records are about multidisciplinary anti-trafficking professionals, such as health care professionals, child welfare professionals, and other service providers, who participate in NHTTAC T/TA offerings.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records consist of participant files. The information technology system that NHTTAC uses to maintain the files allows for participant file information to be collected through structured fields, open text fields, and document attachments. Files include identifiable information about participants, including their name (first, last), mailing address, email, and phone number, and may also include information about certificates received (*e.g.* training completion confirmations), and self-reported demographic information such as race/ethnicity, date of birth, gender identity, employment status, education history, employment history, professional history, language proficiency, user login name and password (user credentials), responses to requests for feedback on NHTTAC T/TA offerings, and T/TA needs assessment responses submitted on behalf of the participant or the participant's professional organization.

RECORD SOURCE CATEGORIES:

Most records are provided directly by the NHTTAC T/TA participant. Continuing education credits are issued by NHTTAC based on records in the online system confirming that the individual completed SOAR *Online* trainings. T/TA needs assessment responses may be provided by the individual participant, or representatives of the participant's professional organization.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures authorized by statute in the Privacy Act

at 5 U.S.C. 552a(b), HHS may disclose records about an individual participant from this system of records for these routine uses:

1. *Disclosure to HHS Contractors, Grant Recipients, and Other Agents.* Information may disclosed to contractors, consultants, grant recipients, or other agents engaged by HHS to assist in the accomplishment of an HHS function relating to the purposes of this system of records who need to have access to the records in the performance of their duties or activities for HHS.

2. *Disclosure to Accrediting Bodies.* Information about a SOAR *Online* participant's fulfillment of Continuing Education/Continuing Medical Education (CE/CME) credits may be reported to the appropriate accrediting bodies.

3. *Disclosure to Congressional Office.* Information may be disclosed to a congressional office from the record of an individual in response to a written inquiry from the congressional office made at the written request of the individual.

4. *Disclosure for Monitoring Waste, Fraud, or Abuse Purposes.* Information may be disclosed to another Federal agency or instrumentality of any governmental jurisdiction within or under the control of the United States (including the State or local governmental agency) that administers or has the authority to investigate potential fraud, waste, or abuse in federally-funded programs, when disclosure is deemed reasonably necessary by HHS to prevent, deter, discover, detect, investigate, sue with respect to defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

5. *Disclosure in the Event of a Security Breach Experienced by HHS.* Information may be disclosed to appropriate agencies, entities, and persons when (1) HHS suspects or has confirmed that there has been a breach of the system of records; (2) HHS has determined, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HHS' efforts to respond to the suspected or confirmed breach, or to prevent, minimize, or remedy such harm.

6. *Disclosure to Assist Another Agency Experiencing a Breach.* Information may be disclosed to another federal agency or federal entity, when HHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach, or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in electronic media format, in a web-based application. Feedback records may be maintained in paper form before being entered in the web-based system.

POLICIES AND PRACTICIES FOR RETRIEVAL OF RECORDS:

NHTTAC retrieves records about a participant by the participant's name (first, last), address, phone number, and email address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The records are currently unscheduled. Unscheduled records must be retained indefinitely pending the agency's submission, and the National Archives and Records Administration (NARA) approval, of a disposition schedule. OTIP is currently coordinating with the HHS Office of the Chief Information Officer (OCIO) to develop a Records Control Schedule (RCS) appropriate for these records. OTIP currently plans to propose a retention period of approximately 10 years for the records.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS Information Systems Security and Privacy Policy (IS2P), all pertinent National Institutes of Standards and Technology (NIST) publications, and OMB Circular A–130 Managing Information as a Strategic Resource. The system leverages cloud service providers that maintain an authority to operate in accordance with applicable laws, rules, and policies, including Federal Risk and Authorization Management Program (FedRAMP) requirements.

The NHTTAC system will be hosted within the FedRAMP Amazon Web Services (AWS) Cloud Platform. Only members of the NHTTAC team are granted access to the web-based system and to any feedback records that are in paper form. Any paper feedback records are maintained in a locked filing cabinet with limited access until entered into the web-based system. Authenticated users within the system have access to review and edit their own PII. Authenticated users in roles with elevated permissions will have access to larger amounts of PII that is specific to certain system purposes. The elevated privilege accounts are associated with specific system features and are granted only to federal OTIP staff or the NHTTAC contractors. The administrator account, Admin Only, is limited to administrative activity only and does not allow for other activity within the application. This role is held by NHTTAC contractors and OCIO personnel. Administrators will have access to PII to support system setup, configuration, testing, monitoring, and other data/system administration. The administrative security controls employed include adhering to ACF, or HHS, policies and procedures around security and privacy; leveraging role-based system access to control the amount of PII available to a user; annual security training, and access to a user manual describing data entry procedures to help maintain the data integrity. The technical controls are shared between the system and the AWS platform. The system provides controls including multi-factor authentication for all users to include Personal Identity Verification (PIV) login capability; and AWS provides infrastructure controls including secure network access points. PII is encrypted at rest within the database, file system, and object storage resources using Advanced Encryption Standard algorithm in Galois/Counter Mode (AES–GCM), with 256-bit secret keys. PII is also encrypted in transit via secure hypertext transfer protocol (HTTPS) using Transport Layer Security (TLS) services provided by Federal Information Processing Standard (FIPS) 140–2 validated cryptographic modules. The physical controls will all be inherited by the AWS platform and include the following: Restricting physical access to the data center both at the perimeter and at building ingress points through the help of video surveillance, intrusion detection systems, and 2 rounds of two-factor authentication for each individual accessing a data center floor. Visitors and contractors are required to have ID, sign-in with building security, and be escorted by an authorized staff at all times; Fire detection and suppression systems; Uninterruptible Power Supply (UPS); Climate and Temperature

control; Preventative maintenance. Staff are responsible for notifying the ACF Incident Response Team (IRT) in the event that a suspected or known breach has occurred. The ACF IRT will follow standard operating procedures for handling a privacy incident that involves a breach of PII.

RECORD ACCESS PROCEDURES:

Participants who are authenticated users of the web-based system have the ability to access information about them in that system. Otherwise, participants seeking access to records about them in this system of records must submit a written access request to the relevant System Manager identified in the ''System Manager(s)'' section of this SORN. The request must contain the requester's (participant's) full name, address, telephone number and/or email address, date of birth, and signature, and should identify the state, Tribe, or territory where the requester participated in the NHTTAC T/TA offering.

So that HHS may verify the requester's identity, the requester's signature must be notarized, or the request must include the requester's written, signed certification that the requester is the individual who the requester claims to be and that the requester understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000.

CONTESTING RECORD PROCEDURES:

Participants who are authenticated users of the web-based system have the ability to amend identifying and descriptive information about them in the system, which they entered in the system. Otherwise, participants seeking to amend records about them in this system of records must submit a written amendment request to the relevant System Manager identified in the ''System Manager(s)'' section of this SORN, containing the same information required for an access request. The request must include verification of the requester's (participant's) identity in the same manner required for an access request; must reasonably identify the record and specify the information contested, the corrective action sought, and the reasons for requesting the correction; and should include supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NHTTAC provides support for individuals who indicate concerns that information about them has be inappropriately obtained, used, or disclosed, or is inaccurate. To support initial reporting of concerns, the web-based system includes contact information for NHTTAC support staff on the home page. Once contacted, NHTTAC will establish an issue/ticket associated with the concern, and track progress towards issue resolution within a separate internal help desk system monitored by the NHTTAC support staff. The participant will be contacted via his or her provided contact information (email or phone) upon initiation of the ticket, as progress is made, and upon resolution of the issue.

NOTIFICATION PROCEDURE:

Participants who are authenticated users of the web-based system have the ability to access the system to determine if it contains records about them. Otherwise, participants who wish to know if this system of records contains records about them should submit a written notification request to the relevant System Manager identified in the ''System Manager(s)'' section of this SORN. The request must contain the same information required for an access request and must include verification of the requester's (participant's) identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2024–09343 Filed 5–1–24; 8:45 am]

BILLING CODE 4184–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcing the Intent To Award a Single-Source Supplement for the Puerto Rico Disaster Assistance Grant Program

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Puerto Rico Ombudsman Office for the Elderly (PROOE) for the project Puerto Rico Disaster Assistance Grant which is through the Older Americans Act, Disaster Assistance for State Units on Aging (SUAs) and Tribal Organizations in Major Disasters Declared by the President and the Consolidated Appropriations Act, 2023.

DATES: The supplement award will be issued to extend the project period to May 1, 2023, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Kathleen Votava, U.S. Department of Health and Human Services, Administration for Community Living, Center for Regional Operations: telephone (202) 795–7603; email*kathleen.votava@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this program, as set forth in Section 310(a)(1) of the Older Americans Act (OAA) is to provide funding to the aging network for disaster-related items in areas receiving a Major Disaster Declaration by the President under the Robert T. Relief and Emergency Assistance Act, where funds may only be used in those areas designated in the Disaster Declaration. These funds are used by the aging network in recovery so that they can resume operations to support older adults and their caregivers. The overall goals of the program are as follows:

1. Provide disaster relief reimbursements to States/Territories (or to any tribal organization receiving a grant under title VI), upon application, for funds such State makes available to area agencies on aging (and/or aging network) in such State (or funds used by such tribal organization) for the delivery of supportive services (and related supplies) during any major disaster declared by the President in accordance with the Robert T. Stafford Relief and Emergency Assistance Act. In addition, provide disaster relief reimbursements for expenses related to the consequences of Hurricanes Fiona and Ian.

2. Provide funds for the aging network to deliver the following Older Americans Act (OAA) Title III types of gap-filling services following a disaster: emergency meals and medications, outreach, information and assistance, counseling, case management, advocacy on behalf of older persons unable or reluctant to speak for themselves, and transportation.

3. Assist the aging network in restoring their capacity and operations after a disaster in order that they may be able to help older adults and caregivers in their communities.

The administrative supplement for FY 2024 will be in the amount of $7,809,231, bringing the total awards made in FY 2023 and FY 2024 to $9,779,231. The supplement will provide sufficient resources to enable the grantee, PROOE, and their partners to continue to address the significant

needs of Hurricane Fiona older adult survivors living in Puerto Rico and expand the reach and effectiveness of this project by:

- Expanding the grantee's project to restore operations impacted by Hurricane Fiona to additional multipurpose senior centers, including installing solar panels, generators, and cisterns, as well as replenishing the supply of emergency meals for older adults;
- Advancing the capacity of the broader aging services network to deliver services to older adults and their caregivers who were impacted by Hurricane Fiona by continuing to identify and address the most critical needs; and
- Increasing outreach, evaluation, technical assistance, and sub-grantee monitoring and financial oversight activities.

The supplement will accomplish the goals of the program using the following approaches:

- *Partnerships* are essential for delivering programs and services vital to help older adults remain in their communities. PROOE's partnership with the aging network, including multipurpose senior centers, is critical to allow services and programs to be provided in communities at the local level, especially in recovery from disasters.
- *Community-based resources, such as multipurpose senior centers,* provide congregate meals, home delivered meals, evidence-based disease prevention and health promotion services, outreach, information and referral services, socialization as well as many other supports for older adults in their local communities. In Puerto Rico, these centers often provide an access point for healthcare, including offering nursing care to and housing medications that need refrigeration for community-dwelling older adults.
- *Stewardship* is key to any project. The supplement will enable PROOE to increase stewardship over the sub-grant process to manage expanded work and enhance program oversight, monitoring, evaluation, and additional activities proportional to the increased funding and expectations resulting from this supplement.

Program Name: Puerto Rico Disaster Assistance Grant.

Recipient: Puerto Rico Ombudsman Office for the Elderly (PROOE).

Period of Performance: The supplement award will be issued to extend the project period to May 1, 2023, through September 30, 2025.

Total Award Amount: $ 9,779,231.

Award Type: Cooperative Agreement Supplement.

Basis for Award: The Puerto Rico Ombudsman Office for the Elderly (PROOE), the State Unit on Aging (SUA), is currently funded to carry out the objectives of the project entitled Puerto Rico Disaster Assistance Grant for the period of May 1, 2023, through September 30, 2024. Since project implementation began in 2023, the grantee has accomplished a great deal. This supplement will enable the grantee to carry their work even further, serving more older adult survivors of Hurricane Fiona by expanding their project to additional senior centers in local communities. The additional funding will not be used to begin new projects or activities. The PROOE is uniquely positioned to complete the work called for under this project. PROOE is the designated SUA and administers the Older American Act programs and services to support older adults living in the community as well as their caregivers. PROOE's partners include the Territory's network of senior centers and local communities, many of which are in rural areas. Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the older adults being served by this project could be negatively impacted by a disruption, thus posing the risk of re-traumatization and further negative impacts on health and wellbeing in their recovery from Hurricane Fiona. If this supplement is not provided, the project would be less able to address the significant unmet health and social support needs of additional older adult survivors and their caregivers. Similarly, the project would be unable to expand its current reach. Finally, providing this supplement to PROOE will allow for the greater realization of Congress' intent in the Older Americans Act which includes targeting older individuals with greatest economic need (including low- income minority individuals and older individuals residing in rural areas) and older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas) to receive services under this Act, as well as targeting of services to older adult individuals at risk for institutional placement to permit such individuals to remain in home and community-based settings.

Statutory Authority: 42 U.S.C. 3030; Pub. L. 117–328, 136 Stat. 4459.

Dated: April 29, 2024.

Allison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–09542 Filed 5–1–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0394]

Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry (GFI) #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' This guidance is intended to clarify FDA's requirements and recommendations with respect to heritable intentional genomic alterations (IGAs) in animals. The guidance is being issued as one of two companion documents. This guidance, entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals. This means that for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get approval before marketing their product. For other types of IGAs in animals that do go through the approval process, the companion draft guidance document, GFI #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the approval process applies to heritable IGAs in animals.

DATES: The announcement of the guidance is published in the **Federal Register** on May 2, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2008–D–0394 for ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine (HFV–108), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2017 (82 FR 6561), FDA published the notice of availability for a draft GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' giving interested persons until April 19, 2017, to comment on the draft guidance. On April 13, 2017, we published a notice announcing the extension of the comment period to June 19, 2017 (82 FR 17844). FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. As noted, this guidance is intended to clarify our risk-based regulatory approach for developers of heritable IGAs in animals.

The guidance is being issued as one of two companion documents. GFI #187A, ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based approach to the oversight of IGAs in animals. This means that, for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get FDA approval before marketing their product. These are IGAs in animals and animal products for which FDA finds that we understand the product's risks for the specified intended use, any identified risks are appropriately mitigated, and we have no further questions for which we would need to see additional data to address. The guidance explains that FDA's approach is risk-based and ranges from:

• Category 1 products for which we do not expect developers to consult with us prior to marketing an animal containing an IGA where the risk is best understood and mitigated; to

• Category 2 products for which we may not expect developers to submit an application for approval of the IGA if, after looking at data submitted about that product's risk, we find that we understand the product's risks for the specified intended use, any identified risks are appropriately mitigated, and we have no further questions for which we would need to see additional data to address; to

• Category 3 products for which FDA will review and, where the data supports it, approve a product using data requirements that are proportionate to the risk associated with the particular product.

Draft GFI #187B, ''Heritable Intentional Genomic Alterations in Animals: The Approval Process,'' whose notice of availability is published elsewhere in this edition of the **Federal Register**, describes how the FDA approval process applies to heritable IGAs in animals.

FDA received comments on the draft guidance that came from industry (companies that produce IGAs and trade associations), individual consumers, academics, non-governmental organizations (consumer, environmental), other Federal and State government agencies, and individual developers of IGAs in animals. In the **Federal Register** notice announcing availability of the draft guidance, FDA posed questions regarding whether there

are categories of IGAs in animals that pose less risk and, if so, what data or information supports that contention. No commenters provided data to address the Agency's questions other than scientific literature references that were not directly applicable or conclusive.

In the notice announcing availability of the draft guidance, FDA also asked for comment on the appropriate terminology for animals with intentional genomic alterations. Commenters expressed different preferences, but there was no general consensus on an appropriate term. FDA has adopted ''intentional genomic alteration'' or ''IGA'' in animals as the term it will use to refer to intentional genomic alterations in animals regardless of whether they are developed with genetic engineering, including genome editing, or some other modern molecular technology. This term is simple and sufficiently broad to encompass intentional genomic alterations achieved through means that currently exist and those yet to be developed. Moreover, section 740(d)(4)(B) of the Federal Food, Drug, and Cosmetic Act uses this term (21 U.S.C. 379j-12(d)(4)(B)). However, the scope of the guidance does not include induction of polyploidy by heat, pressure, or chemical treatment, or selective breeding or other assisted reproductive technologies. Non-heritable intentional genomic alterations in animals are also outside the scope of this guidance document.

Changes FDA has made in response to comments include:

- Reorganization and use of plain language to make FDA's regulatory approach clearer to stakeholders;
- Expansion of IGAs for which FDA may decide it does not expect submission of an application for approval following a review of data and a determination that the IGA meets the Category 2 description in the guidance. The new types of IGAs include:
  - IGAs that are equivalent to genomic sequences that are found in animals of the same species with a history of safe use in animal agriculture food production and
  - IGAs that are equivalent to what could be theoretically achieved through conventional breeding under certain conditions,

including that the IGAs are not expected to result in changes to food composition and their intended use does not include any effect on disease or other health outcome;

- Clarification that if you are:
  - ;a farmer, grower, or other entity that just has animals with IGAs that FDA has approved or determined are Category 2 on your farm or other premises, including the offspring of those animals,
  - and you are not the developer of the IGA in the animal or marketing the animals with any new claims,

then, as a general matter, you do not have to register or list with FDA and you can engage in your ordinary activities (*e.g.,* breeding, growing, etc.) without contacting FDA; and

- Clarification that those who breed an animal containing an IGA that FDA has approved or has determined is Category 2:
  - with another animal containing an IGA that FDA has approved or also determined is Category 2 or
  - with an animal that does not contain an IGA

and make no new claims do not need to contact FDA and nothing further is required.

The guidance announced in this notice finalizes the draft guidance dated January 2017.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information regarding environmental analysis in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of information regarding applications in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information regarding investigational exemptions in 21 CFR part 511 have been approved under OMB control number 0910–0117.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09278 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2648]

Heritable Intentional Genomic Alterations in Animals: The Approval Process; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #187B entitled ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' This draft guidance is intended to clarify FDA's requirements and recommendations for developers of intentional genomic alterations (IGA) in animals. The draft guidance is being issued as one of two companion documents. ''Heritable Intentional Genomic Alterations in Animals: The Approval Process'' describes how the FDA approval process applies to heritable IGAs in animals. FDA is issuing GFI #187B as a draft guidance to solicit comments that will enable the Agency to update, and make as efficient as possible, the approval process for IGAs in animals. In addition, FDA requests comments on questions that it intends to address in the final version of this guidance document. The companion final guidance, GFI #187A entitled ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' describes FDA's risk-based regulatory approach to the oversight of heritable IGAs in animals. This means that, for people or companies developing certain types of IGAs in animals, FDA may not expect them to submit an application or get approval before marketing their product.

DATES: Submit either electronic or written comments on the draft guidance by July 31, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–2648 for ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Adam Moyer, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–2319, *Adam.Moyer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 19, 2017 (82 FR 6561), FDA published the notice of availability for a draft GFI #187 entitled ''Regulation of Intentionally Altered Genomic DNA in Animals'' giving interested persons until April 19, 2017, to comment on the draft guidance. On April 13, 2017, we published a notice announcing the extension of the comment period to June 19, 2017 (82 FR 17844). FDA received numerous comments on the draft guidance GFI #187 and those comments were considered as the guidance was revised. As noted, this draft guidance, GFI #187B, is intended to explain how FDA's approval process applies in the context of products related to heritable IGAs in animals.

The draft guidance is being issued as one of two companion documents. Draft GFI #187B, ''Heritable Intentional Genomic Alterations in Animals: The Approval Process,'' describes how the FDA approval process applies to heritable IGAs in animals. Final GFI #187A, ''Heritable Intentional Genomic Alterations in Animals: Risk-Based Approach,'' whose notice of availability is published elsewhere in this edition of the **Federal Register**, describes FDA's risk-based approach to the oversight of IGAs in animals.

FDA received and reviewed comments on the draft guidance that came from industry (companies that produce IGAs and trade associations), individual consumers, academics, non-governmental organizations (consumer, environmental), other Federal and State government agencies, and individual developers of IGAs in animals. Among the changes made to the draft guidance, we have:

- Indicated our willingness to consider multiple heritable IGAs or a single IGA in multiple lines or breeds of animals of the same species under a single application;
- Clarified that FDA's review of applications is subject to specific timeframes;
- Acknowledged that it may not be feasible to gather data on multiple generations and encourage developers of heritable IGAs in animals to contact FDA to discuss alternative approaches of demonstrating durability;
- Indicated that alternative disposition methods for investigational animals may be acceptable if the sponsor contacts FDA's Center for Veterinary Medicine;
- Further described post-market records and reports requirements and clarified who they apply to; and
- Provided additional information on establishment registration requirements, including explaining that, as a general matter, pet stores, farms, or other animal production facilities do not have to register or list with FDA and can engage in ordinary activities (*e.g.,* breeding, growing, etc.) without contacting FDA.

FDA is issuing this draft guidance to solicit public comment that will further

improve it. To help inform our thinking as we begin the process of further updating the guidance, we invite comment on the following questions:

1. What are some alternative strategies for providing data that would support approval of heritable IGAs in animals?

a. How can a developer demonstrate the durability of a heritable IGA over time in situations where collection of data on multiple generations of animals is difficult or not possible?

b. What are possible strategies a developer could utilize to address the approval requirements for multiple heritable IGAs (*e.g.,* multiple iterations of the same alteration resulting in the same intended phenotype or multiple alterations resulting in more than one intended phenotype) under a single approval?

2. What areas of current good manufacturing practices and good laboratory practices specific to the production of heritable IGAs in animals do you believe need clarification through the publication of additional guidance?

3. Are there process improvements (*e.g.,* combining steps of the approval process) (see page 16, section IV.C. Recommended Process for Completing Pre-approval Assessments for IGAs in Animals, of the guidance) that you believe would make the approval process easier to navigate?

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Heritable Intentional Genomic Alterations in Animals: The Approval Process.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 207 have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0284; and the collections of information in 21 CFR 558.6(a)(4) have been approved under OMB control number 0910–0363.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: April 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09279 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5018]

Angela Maria Giron: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Angela Maria Giron, M.D. from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Giron was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Dr. Giron was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 16, 2024 (30 days after receipt of the notice), Dr. Giron has not responded. Dr. Giron's failure to respond and request a hearing constitutes a waiver of Dr. Giron's right to a hearing concerning this matter.

DATES: This order is applicable May 2, 2024.

ADDRESSES: Any application by Dr. Giron for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–5018. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product. On September 11, 2023, Dr. Giron was convicted as defined in section 306(l)(1) of the FD&C Act in the United States District Court for the Southern District of Florida-Miami Division when the court accepted her plea of guilty and entered judgment against her for one count of Conspiracy to defraud the United States in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information and the Factual Proffer in Support of Guilty Plea, from Dr. Giron's case, she was a licensed physician and served as a clinical investigator at AMB Research Center, Inc. (AMB), a medical clinic located in Miami, Florida. AMB conducted clinical trials of new drugs for pharmaceutical companies and other sponsors. AMB entered into a Clinical Trial Agreement with a Clinical Research Organization (CRO) that managed and oversaw a clinical trial designed to evaluate the safety and efficacy of an investigational drug intended to treat persons with Clostridium difficile-associated diarrhea (CDAD clinical trial) on behalf of a sponsor (a pharmaceutical company). Dr. Giron agreed to serve as the clinical investigator, also known as the principal investigator, for the CDAD clinical trial at AMB and signed the Form FDA 1572, Statement of Investigator, for the CDAD clinical trial. By signing the Form FDA 1572, she knew that as the clinical investigator she was required to, among other things, (1) conduct the CDAD clinical trial according to the study protocol and in compliance with all applicable Federal regulations; (2) personally conduct and supervise the CDAD clinical trial; (3) obtain informed consent from the subjects; and (4) comply with the clinical trial protocol and applicable Federal regulations relating to obtaining informed consent and the informed consent process.

As the CDAD principal investigator, Dr. Giron was also responsible for complying with all requirements regarding the eligibility of subjects in accordance with the protocol; dispensing study medication; collecting and reporting data; reporting adverse events; and ensuring that all employees working on the study met those same obligations. Dr. Giron was also required to prepare and maintain case histories which were records relating to the CDAD clinical trial. These case histories for each subject participating in the CDAD clinical trial included informed consent forms and medical records, drug dispensation records, and records of all observations and other data pertinent to the CDAD clinical trial.

For purposes of obtaining money from the Sponsor and/or CRO, Dr. Giron, along with her co-conspirators, created false and fraudulent study records. For example, electronic case record files (eCRFs) falsely represented that the subjects completed the informed consent form (ICF) process, which required Dr. Giron to review the ICF with each subject and personally obtain the subject's written informed consent. In truth and fact, Dr. Giron did not obtain written informed consent for any of the 22 subjects enrolled in the CDAD clinical trial. Dr. Giron knew that the study subjects did not participate in the CDAD clinical trial in accordance with the study protocol and applicable Federal regulations.

In addition, along with her co-conspirators, Dr. Giron falsified data of enrolled subjects in the CDAD clinical trial. For example, Dr. Giron did not conduct the required clinical investigator assessments at the second, third and fifth visits. She also knew that falsified and fraudulent information was submitted in case report forms and eCRFs falsely representing she had completed those required assessments according to the protocol. Furthermore, Dr. Giron also knew that false information and data was submitted in the case report forms and eCRFs representing that the subjects had satisfied eligibility criteria to participate in the CDAD clinical trial, received and taken the study medication, and completed the required documents and journals.

After an on-site audit of AMB by the Sponsor in April 2017, the Sponsor notified the FDA in writing of potential scientific misconduct by AMB. The Institutional Review Board for the CDAD clinical trial sent AMB a copy of the Sponsor's notification to FDA. Dr. Giron, along with a co-conspirator, signed a letter entitled ''Site response to the Notification of Potential Scientific Misconduct.'' At the time of signing that response letter Dr. Giron knew that it contained materially false and fraudulent representations including that (1) she was present for all subjects' informed consent and gave each subject the time to understand, read, and resolve any questions prior to signing the informed consent form; (2) AMB took special care with ICF signatures and the ICF process to ensure that subjects understood the study and its risks and could make an informed decision whether to participate; (3) all participating subjects had completed the study treatment and follow up visits; and (4) she and AMB site staff acted in accordance with the study protocol to the best of their knowledge. Dr. Giron received $58,119.60 in proceeds for the CDAD clinical trial. AMB received more than $250,000 for the CDAD clinical trial.

As a result of this conviction, FDA sent Dr. Giron, by certified mail, on January 10, 2024, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A), that Dr. Giron was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug

product. The proposal informed Dr. Giron of the proposed debarment and offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Giron received the proposal and notice of opportunity for a hearing on January 17, 2024. Dr. Giron failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Angela Maria Giron, M.D. has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product.

As a result of the foregoing finding, Dr. Giron is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C, (335a(c)(2)(A)(ii))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Dr. Giron during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Giron provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Dr. Giron during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: April 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09528 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2024–N–1464]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements of our regulations concerning new animal drugs for investigational use.

DATES: Either electronic or written comments on the collection of information must be submitted by July 1, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 1, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–1464 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Use—21 CFR 511

OMB Control Number 0910–0117—Extension

This information collection helps support implementation of Agency statutory and regulatory requirements regarding the approval of new animal drugs. FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support a NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping to qualify for the exemption from section 512(a) of the FD&C Act. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

Our regulations require that certain information be submitted to us in a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to help ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bioresearch Monitoring Program. This program permits us to monitor the validity of the studies and to help ensure the proper use of the drugs is maintained by the investigators.

Sponsors use eSubmitter, a secure online, question-based submission tool, to submit the NCIE electronically (*https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs*).

Description of Respondents: Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government (*i.e.,* sponsors of investigational new animal drugs). Investigators may include individuals from these entities, as well as research firms and members of the medical professions. With respect to this information collection, the term respondent includes sponsors who are subject to user fees and sponsors who are not subject to user fees.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4), 511.1(b)(5) 511.1(b)(6) 511.1(b)(8)(ii), and 511.1(b)(9); submissions of NCIE, data to obtain authorization, any additional information upon request of FDA, reporting of findings that may suggest significant hazards, and reporting by importers of investigational new animal drugs for clinical investigational use in animals ...	257	5.70	1,466	1.12	1,634

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3), 511.1(b)(3), 511.1(b)(7), and 511.1(b)(8)(ii); Maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug, or feed containing the same is shipped and the date, quantity, and batch or code mark of each shipment and delivery; maintain records of the investigation and all reports received by a sponsor from investigators	257	17.44	4,482	2.57	11,519

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

The NCIE must contain, among other things, the following specific information: (1) identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4)). If the new animal drug is to be used in food-producing animals (*e.g.,* cattle, swine, chickens, fish, etc.), certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)).

If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)).

We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 257 respondents. We use this estimate throughout both tables to calculate the ''number of responses per respondent'' by dividing the total annual responses by number of respondents. The burden we attribute to reporting and recordkeeping activities is assumed to be distributed among the individual elements of the respective information collection activities.

Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. There is a decrease in the total burden hours of 2,401, which we attribute to a decrease in the number of respondents as well as the number of annual responses and records.

Dated: April 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09526 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1940]

Request for Nominations of a Nonvoting Representative of the Interest of Tobacco Growers on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for a nonvoting representative of the interests of the tobacco growers to serve on the Tobacco Products Scientific Advisory Committee (TPSAC), in the Center for Tobacco Products. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and

individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups. A nominee may either be self-nominated or nominated by an organization. In addition, FDA is requesting that any industry organizations interested in participating in the selection of a nonvoting representative of the interests of the tobacco growers industry to serve on the TPSAC, notify FDA in writing. Nominations will be accepted for either the representative to serve on TPSAC or for the selection group effective with this notice.

DATES: Nomination materials for prospective candidates should be sent to FDA by June 3, 2024. Concurrently, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of the tobacco growers industry must send a letter stating that interest to FDA by *June 3, 2024* (see sections I and II of this document for further details).

ADDRESSES: All nominations for nonvoting representatives of the interests of the tobacco growers industry may be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm.*

All statements of interest from industry organizations interested in participating in the selection process of nonvoting representatives of the interests of the tobacco growers industry nomination should be sent to Serina Hunter-Thomas (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), email: *Serina.Hunter-Thomas@fda.hhs.gov.*

Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a nonvoting representative of the interests of the tobacco growers industry on the TPSAC.

I. General Description of the Committee Duties

The TPSAC advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The TPSAC reviews and evaluates safety, dependence, or health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting representative of the interests of the tobacco growers industry. Nominations must include a current résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. The nomination should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

III. Selection Procedure

The Agency is also seeking names of organizations to participate in the selection of the nonvoting representative of the interests of the tobacco growers industry. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent growers industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest in participating in the selection group, attaching a complete list of all organizations participating in selection; and a list of all nonvoting nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations on the selection group to confer with one another and to select a candidate and an alternative as backup, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent growers industry interests for the TPSAC. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent growers industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and part 14, relating to advisory committees.

Dated: April 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09532 Filed 5–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 1, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The Maternal, Infant, and Early

Childhood Home Visiting Program Quarterly Performance Report OMB No. 0906–0016—Revision.

Abstract: This request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Quarterly Performance Report. The MIECHV Program is administered by the Maternal and Child Health Bureau (MCHB) within HRSA in partnership with the Administration for Children and Families, and provides support to all 56 States and jurisdictions, as well as Tribes and Tribal organizations. Through a needs assessment, States, jurisdictions, Tribes, and Tribal organizations identify target populations and select the home visiting service delivery model(s) that best meet their needs. In response to awardee feedback, HRSA is proposing the following revisions to the data collection forms to reduce administrative burden related to this performance report:

- Form 4, Table A.2: Remove Column D: Zip Codes
- Form 4, Definition of Key Terms: Update definitions for Table A.2
- Form 4: Remove Section B

Need and Proposed Use of the Information: HRSA uses quarterly performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, State, and local level. HRSA is seeking to remove collection of a variable and update key terms given this deletion.

Likely Respondents: MIECHV Program awardees that are States, jurisdictions, and, where applicable, nonprofit organizations providing home visiting services within States.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 4: Section A—Quarterly Performance Report	56	4	224	21	4,704
Total	56		224		4,704

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–09533 Filed 5–1–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: COVID–19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities, Office of Management and Budget No. 0906–0083—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement to provide opportunity for public comment on proposed data collection projects per the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than July 1, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: COVID–19 Provider Relief Programs Single and Commercial Audits and Delinquent Audit Reporting Submission Activities, OMB No. 0906–0083—Extension.

Abstract: The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136); the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139); the Coronavirus Response and Relief Supplemental Appropriations Act (Pub. L. 116–260); the Families First Coronavirus Response

Act (Pub. L. 116–127); and the American Rescue Plan Act of 2021 (Pub. L. 117–2) provided the Department of Health and Human Services the authority to administer the Provider Relief Programs (PRP) (*e.g.,* Provider Relief Fund; American Rescue Plan Act Rural Distribution; COVID–19 Coverage Assistance Fund; and COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured). The Department of Health and Human Services delegated the authority for these programs to HRSA. The PRP issued payments to eligible health care providers for expenses or lost revenues attributable to COVID–19 and claims reimbursement for COVID–19 testing, treatment, and vaccine administration for uninsured and COVID–19 vaccine administration for underinsured individuals. Recipients of these funds agreed to the Terms and Conditions applicable to each Program, which require, among other Terms, compliance with reporting requirements as specified by the Secretary of Health and Human Services. Recipients are eligible health care providers who include public entities, Medicare or Medicaid enrolled suppliers and providers, and for-profit and non-profit entities that provide diagnosis, testing, vaccination, or care for individuals with possible or actual cases of COVID–19. The Single Audit Act requires entities that expend $750,000 or more of federal assistance during the entity's fiscal year to conduct an independent audit. Requirements for these audits are set forth in regulations at 45 CFR subpart F. Requirements differ for non-profit and commercial/for-profit entities, and non-profit entities are required to submit their audits to the Federal Audit Clearinghouse. HRSA has established a Commercial Audit Reporting Portal to collect audits from commercial/for-profit organizations. In late calendar year 2023, HRSA developed a delinquent audit follow-up process to ensure that all providers required to submit an audit do so. The delinquent audit follow-up process includes educating PRP recipients on the 45 CFR 75 subpart F requirements and following up on overdue audit report submissions. In February 2024, OMB approved HRSA's emergency ICR for the Commercial Audit Reporting Portal and the delinquent audit follow-up process. Collectively, these activities will help ensure the fiscal and program integrity of the PRP.

Need and Proposed Use of the Information: HRSA will use the collected information to ensure all PRP recipients who expended over $750,000 in funding during the recipient's fiscal year submit an audit and resolve audit findings, including recovery of any funds used not in accordance with the Terms and Conditions of the programs.

Likely Respondents: PRP recipients who expended over $750,000 in funding during their fiscal year.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Provider Relief Bureau Commercial Audit Reporting Portal	21,000	1	21,000	0.75	15,750
Delinquent Audit Follow-up Attestation	21,000	2	42,000	0.25	10,500
Questioned Cost Attestation	7,000	10	70,000	5.00	350,000
Total	49,000		133,000		376,250

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–09466 Filed 5–1–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Seniors and Disasters Public Meeting

AGENCY: Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Advisory Committee on Seniors and Disasters (NACSD) will conduct a public meeting on Monday, May 20, 2024 (2:30 p.m.–4:30 p.m. ET). Notice of the meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act (FACA). The NACSD is required by section 2811B of the Public Health Service Act (PHS) Act (42 U.S.C. 300hh–10c), as amended by the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA), Public Law 116–22, and governed by the provisions of the Federal Advisory Committee Act (FACA). The NACSD provides expert advice and guidance to the U.S. Department of Health and Human Services (HHS) regarding all-hazards public health and medical preparedness, response, and recovery activities related to meeting the unique needs of older adults. ASPR manages and convenes the NACSD on behalf of the Secretary of HHS. The NACSD will discuss and deliberate questions posed by ASPR on climate and health equity.

Procedures for Public Participation: The public and expert stakeholders are invited to observe the meeting either in-person or virtually and pre-registration

is required. The pre-registration link and a more detailed agenda will be available on the NACSD website. Anyone may submit questions and comments to the NACSD by email (*NACSD@hhs.gov*) before the meeting. American Sign Language translation and Communication Access Real-Time Translation will be provided.

We would like to specifically seek input from the public on climate and health equity considerations in disaster training as well as opportunities and strategic priorities for national public health and medical preparedness, response, and recovery specific to the needs of older adults. Representatives from industry, academia, health professions, health care consumer organizations, non-federal government agencies, or community-based organizations may request up to five minutes to speak directly to the Committee. Requests to speak to the Committee will be approved in consultation with the Committee Chair and based on time available during the meeting. Requests to speak to the NACSD during the public meeting must be sent to *NACSD@hhs.gov* by close of business on May 15, 2024. Please provide the full name, credentials, official position(s), and relevant affiliations for the speaker and a brief description of the intended topic. Presentations that contain material with a commercial bias, advertising, marketing, or solicitations will not be allowed. A meeting summary will be available on the NACSD website post meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Maxine Kellman; NACSD Designated Federal Official, (202) 260–0047; *NACSD@HHS.GOV.*

The Administrator and Assistant Secretary for Preparedness and Response of ASPR, Dawn O'Connell, having reviewed and approved this document, authorizes Adam DeVore, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Adam DeVore,

Federal Register Liaison, Administration for Strategic Preparedness and Response.

[FR Doc. 2024–09584 Filed 5–1–24; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2023–0036; OMB No. 1660–0033]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; Residential Basement Floodproofing Certificate

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of extension and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. FEMA invites the general public to take this opportunity to comment on an extension of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning information collected for eligible properties insured under the National Flood Insurance Program (NFIP) policies to certify the floodproofing of residential basements.

DATES: Comments must be submitted on or before June 3, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Joycelyn Collins, Underwriting Branch Program Analyst, Federal Insurance Directorate, by email at *Joycelyn.Collins@fema.dhs.gov* or by telephone at (202) 701–3383.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP) is authorized by the National Flood Insurance Act of 1968 (90–448, title XIII) and expanded by the Flood Disaster Protection Act of 1973 (93–234) and requires that FEMA provide flood insurance. FEMA delineates flood zones on a Flood Insurance Rate Map to identify Special Flood Hazard Areas (SFHAs) in a community. 44 CFR 60.3(c)(2) requires that all new construction and substantial improvements of residential structures within SFHA Zones A1–30, AE, AH, and AO zones have the lowest floor, including the basement, elevated to or above the base flood level unless a community-wide exception or site-specific variance is granted. 44 CFR 60.6(a)(7) and 44 CFR 60.6(b)(1) allow communities to apply for an exception when circumstances present a hardship that would not allow for adherence to the requirement for elevation above the base flood level. Exceptions granted under 44 CFR 60.6(c) must meet the conditions specified in the regulation. When owners of residential structures in these zones are seeking flood insurance, they must be certified that the structural design is floodproof.

This proposed information collection previously published in the **Federal Register** on January 31, 2024, at 89 FR 6124 with a 60-day public comment period. One public comment was received, and it did not specifically address the proposed extension of the collection of information on residential basements insured under the NFIP, or otherwise provide information relevant to the Notice. FEMA determined that no change in FEMA's proposed extension of the information collection related to residential basements is required. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Residential Basement Floodproofing Certificate.

Type of Information Collection: Extension of a currently approved information collection.

OMB Number: 1660–0033.

FEMA Forms: FEMA Form FF–206–FY–21–122 (formerly 086–0–24), Residential Basement Floodproofing Certificate.

Abstract: The Residential Basement Floodproofing Certificate is required to certify that floodproofing of a structure in communities approved for Residential Basement floodproofing meets at least minimal floodproofing specifications. Residential structures that receive this certification are granted a discount on flood insurance premiums.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Number of Responses: 10.

Estimated Total Annual Burden Hours: 25.

Estimated Total Annual Respondent Cost: $1,763.

Estimated Respondents' Operation and Maintenance Costs: $5,000.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $191.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2024–09539 Filed 5–1–24; 8:45 am]

BILLING CODE 9111–52–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7086–N–09]

60-Day Notice of Proposed Information Collection: Housing Counseling Agency Activity Reports, OMB Control No.: 2502–0622

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 1, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–3577 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Housing Counseling Agency Activity Reports.

OMB Approval Number: OMB Control No.: 2502–0622.

OMB Expiration Date: 12/31/2024.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–9902.

Description of the need for the information and the proposed use: The purpose of form HUD–9902 is to collect information on HUD Approved Housing Counseling Agency and household activity to assist OHC in analyzing agency performance and program impact information. In addition, the data will help to determine whether Notice of Funding Opportunity (NOFO) grant applicants meet the requirements of the NOFO and provides a method for assignment of points for awarding grant funds on a competitive and equitable basis.

Respondents: Not-for-profit institutions; State, Local or Tribal Government.

Estimated Number of Respondents: 1,614.

Estimated Number of Responses: 6,456.

Frequency of Response: 4 times a fiscal year.

Average Hours per Response: .36.

Total Estimated Burden: 2,324 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2024–09541 Filed 5–1–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6433–N–02]

Request for Information Regarding Iron, Steel, Construction Materials, and Manufactured Products Used in Housing Programs Pursuant to the Build America, Buy America Act; Extension of Comment Period

AGENCY: Office of the Secretary, Department of Housing and Urban Development (HUD).

ACTION: Extension of comment period for request for information.

SUMMARY: On February 13, 2024, the Department of Housing and Urban Development published in the **Federal Register** a document titled, ''Request for Information Regarding Iron, Steel, Construction Materials, and Manufactured Products Used in Housing Programs Pursuant to the Build America, Buy America Act.'' (RFI) The request for comment provided for a 60-day comment period, which ended on April 15, 2024. HUD has determined that a 45-day extension of the comment period is appropriate to allow interested persons additional time to provide responses. HUD is interested in comments relating to the domestic market for products required in housing infrastructure projects that are compliant with the Build America Preference (BAP), especially those detailing domestic materials sourcing, market readiness, other product supply considerations, and whether specific housing products or their components are manufactured in the United States.

DATES: The comment period for the request for comment published on February 13, 2024, at 89 FR 10090, is extended to June 17, 2024.

ADDRESSES: Interested persons are invited to submit comments on the request for information. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov*. To receive consideration as public comments, comments must be submitted through one of two methods, specified below. All submissions must refer to the above docket number and title.

1. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov*. HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

2. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

No Facsimile Comments. Facsimile (FAX) comments will not be accepted.

Public Inspection of Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the submissions must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications relay-service-trs*.

Copies of all submissions are available for inspection and downloading at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Faith Rogers, Department of Housing and Urban Development, 451 Seventh Street SW, Room 10126, Washington, DC 20410–5000, at (202) 402–7082 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications relay-service-trs*. HUD encourages submission of questions about this document be sent to BuildAmerica *BuyAmerica@hud.gov*.

SUPPLEMENTARY INFORMATION: The Build America, Buy America Act (BABA), enacted on November 15, 2021, establishes a domestic procurement preference, the BAP, which HUD must implement to ensure that iron, steel, manufactured products, and construction materials used for infrastructure projects are produced in the United States. HUD has worked to develop an implementation plan across its Federal Financial Assistance (FFA) programs, including publishing a ''Request for Information Relating to the Implementation of the Build America, Buy America Act'' on June 1, 2022. In furtherance of its implementation plan, HUD published in the **Federal Register** a document titled ''Request for Information Regarding Iron, Steel, Construction Materials, and Manufactured Products Used in Housing Programs Pursuant to the Build America, Buy America Act.'' The request for information solicits comment input to improve HUD's understanding of the current state of the domestic market for products required in housing infrastructure projects.

While the request for information originally provided for a 30-day comment period, in consultation with the Office of Management and Budget's Made in America Office HUD has determined that extending the public comment period by an additional 45 days will better allow the public to submit comments that will help HUD gather information necessary to fully implement the BAP. Thus, HUD is extending the date for public comment until June 17, 2024.

Aaron Santa Anna,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2024–09489 Filed 5–1–24; 8:45 am]

BILLING CODE 4210–67–P

INTER-AMERICAN FOUNDATION

Sunshine Act Meetings

TIME AND DATE: Tuesday, May 7, 2024, 9:30 a.m.–11:30 a.m.

PLACE: Hybrid with public attendance held virtually.

STATUS: Meeting of the Board of Directors, partially closed to the public.

MATTERS TO BE CONSIDERED: Management team updates.

PORTIONS OPEN TO THE PUBLIC:

- Call to Order
- Overview of Meeting Rules by General Counsel
- Approval of Minutes from October 10, 2023 meeting
- Discussion of management team updates, including FY24 and FY25 budgets, grants management system update, core funding update, fellowships update
- Adjournment

PORTIONS CLOSED TO THE PUBLIC:

CONTACT PERSON FOR MORE INFORMATION: Nicole Stinson, Associate General Counsel, (202) 683–7117 or *generalcounsel@iaf.gov.*

For Dial-in Information contact: Nicole Stinson, Associate General Counsel, *generalcounsel@iaf.gov.*

The Inter-American Foundation is holding this meeting under the Government in the Sunshine Act, 5 U.S.C. 552b and 22 CFR 1004.

Natalia Mandrus,

Associate General Counsel.

[FR Doc. 2024–09346 Filed 4–30–24; 8:45 am]

BILLING CODE 7025–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R7–ES–2024–0004; FXES111607MRG01–245–FF07CAMM00]

Marine Mammal Protection Act; Permit Applications and Issuances

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite public comment on applications for permits to conduct certain activities involving marine mammals for which the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). In addition, we announce permits that we have issued recently in response to prior applications.

DATES: We must receive comments on the new permit applications by June 3, 2024.

ADDRESSES:

Obtaining Documents:

• *Application Materials:* The applications, application supporting materials, and any comments and other materials that we receive are available for public inspection at *https://www.regulations.gov* in Docket No. FWS–R7–ES–2024–0004.

• *Issued Permits:* To access materials pertaining to the permits we have issued, see Permits Issued by the Service under **SUPPLEMENTARY INFORMATION**.

Submitting Comments on the Applications: You may submit comments containing written data or views concerning the taking or importation proposed in each application by one of the following methods:

• *Internet: https://www.regulations.gov*. Search for and submit comments on Docket No. FWS–R7–ES–2024–0004.

• *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R7–ES–2024–0004; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Charles Hamilton, via email at *r7mmmregulatory@fws.gov* or by telephone at 907–786–3800 or 1–800–362–5148. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Background

With some exceptions, the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), prohibits the take and importation of marine mammals and marine mammal products absent Federal authorization. In carrying out our responsibilities under the MMPA, we, the U.S. Fish and Wildlife Service (Service), may authorize such activities via permits after receipt of an application and verification that MMPA statutory and regulatory requirements are met.

Section 104(c) of the MMPA specifies the conditions for authorizing the taking or importation of a marine mammal for purposes of scientific research, public display, or enhancing the survival or recovery of a species or stock under the MMPA.

This notice provides information about two aspects of the MMPA permitting process: application and issuance. At section II, we provide the public with notice of and the opportunity to comment on applications that we have received from entities or individuals to conduct certain activities with marine mammals for which the Service has jurisdiction under the MMPA. At section III, we announce recently issued MMPA permits to entities or individuals in response to prior applications.

II. Applications Available for Public Review

To help us carry out our conservation responsibilities for affected species, and in consideration of section 104(c) of the MMPA, we invite the public and local, State, Tribal, and Federal agencies to comment on the applications listed below before final action is taken. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of these marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

A. Permit Applications Received

We invite comments on the following applications:

Applicant: Matson's Laboratory, Manhattan, MT; Permit No. PER6413229

The applicant requests a permit to import teeth from up to 200 legally harvested Atlantic walrus (*Odobenus rosmarus rosmarus*) from Canada. After analysis, Matson's Lab will provide information on animal ages to be used by governmental authorities in Canada to inform population abundance estimation and survival analyses, along with ensuring that legal harvest of walrus is sustainable and well managed. Once the laboratory analysis is complete, samples will be exported (returned) to Canada. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jason Roehing/MeatEater Inc., Bozeman, MT, Permit No. 5955318

The applicant requests a permit to conduct commercial photography and filming of northern sea otters (*Enhydra lutris kenyoni*) in the wild. This notification covers activities to be conducted by the applicant during the period March through May 2024.

Applicant: North Slope Borough Department of Wildlife, Utqiagvik, AK, Permit No. 0046206

The applicant requests a reissuance of their scientific research permit to (1) collect tissue samples from dead polar bears (*Ursus maritimus*) and Pacific walrus (*Odobenus rosmarus rosmarus*); (2) conduct aerial surveys to detect carcasses of polar bears and Pacific walrus; and (3) conduct noninvasive sampling for eDNA. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: U.S. Fish and Wildlife Service, Marine Mammals Management Office, Anchorage, AK, Permit No. MA82088B–1

The applicant requests an amendment to their scientific research permit to allow the take of polar bears (*Ursus martimus*) by disturbance. The research will be used to evaluate the distance at which wild polar bears on the Beaufort seashore respond to boat traffic. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: U.S. National Park Service, Juneau, AK, Permit No. 14762C

The applicant requests a reissuance of their scientific research permit to (1) conduct aerial photographic surveys to estimate the spatial distribution and abundance of sea otters (*Enhydra lutris kenyoni*) and (2) conduct land-based foraging observations of sea otters in the Glacier Bay, Icy Strait, Cross Sound, outer coast of Glacier Bay, and Yakutat areas of southeastern Alaska. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Windfall Films, London, United Kingdom, Permit No. 9061181

The applicant requests a permit to conduct commercial photography and filming of Pacific walrus (*Odobenus rosmarus divergens*) in the wild. This notification covers activities to be conducted by the applicant during the period May through October 2024.

B. Public Comment Procedures

1. How do I comment on permit applications?

Before issuing any requested permit, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments that we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (a) Those supported by quantitative information or studies; and (b) those that include citations to, and analyses of, the applicable laws and regulations.

2. May I review comments submitted by others?

You may view public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or other Federal law.

3. Who will see my comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

C. Next Steps for Submitted Applications

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed above in this notice, we will publish a subsequent notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *https://www.regulations.gov* and search for ''12345A''.

III. Permits Issued by the Service

We have issued permits to conduct certain activities involving marine mammals and marine mammal products in response to prior permit applications that we received. This notice informs the public that the Service has issued the permits listed in Table 1 below.

The permittees' original permit application materials, along with public comments we received during public comment periods for the applications, are available for review. To locate the application materials and received comments, go to *https://www.regulations.gov* and search for the appropriate permit number (*e.g.,* PER12345) or docket number (*e.g.,* FWS–HQ–IA–2022–0001) provided in table 1.

TABLE 1—MMPA PERMITS RECENTLY ISSUED

Permit No.	Applicant	Permit issuance date	Docket No.
PER0030527	U.S. Geological Survey	10/05/2023	FWS–HQ–IA–2022–0007
PER690038	U.S. Geological Survey	10/19/2023	FWS–HQ–IA–2018–0083
PER84399D	NOAA Fisheries/AFSC/Marine Mammal Laboratory	10/30/2023	FWS–HQ–IA–2022–0102
PER0032559	Alaska Veterinary Pathology Services	01/04/2024	FWS–HQ–IA–2022–0138
PER0040980 (Legacy PRT #84799B)	Texas A&M University	01/12/2024	FWS–HQ–IA–2022–0138

IV. Authority

We issue this notice under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and its implementing regulations.

Peter Fasbender,

Assistant Regional Director for Fisheries and Ecological Services, Alaska Region.

[FR Doc. 2024–09479 Filed 5–1–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[223D0102DM, DS6CS00000, DLSN00000.000000. DX6CS25; OMB Control Number 1093–0012]

Agency Information Collection Activities; Application Requirements for States and Tribes To Apply for Orphaned Well Site Plugging, Remediation, and Restoration Funding Consideration, and Ongoing State and Tribal Reporting Requirements for Funding Recipients

AGENCY: Office of the Secretary of the Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Office of the Secretary of the Interior (Interior), through her delegated office, the Orphaned Wells Program Office (OWPO), proposes to renew and revise an OMB-approved information collection, which is numbered OMB Control Number 1093–0012.

DATES: Interested parties are invited to submit comments on or before July 1, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent to Jeffrey Parrillo, Departmental Information Collection Clearance Officer, U.S. Department of the Interior, 1849 C Street NW, Washington, DC 20240; or by email to *DOI-PRA@ios.doi.gov.* Please reference OMB Control Number ''1093–0012 Orphaned Well Program Office'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this proposed information collection, please contact Ron Lev, Management and Program Analyst, OWPO, by email, at *orphanedwells@ios.doi.gov,* or by phone, at (771) 233–5722.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside of the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8, all information collections require approval. Interior may not conduct or sponsor, and a party is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

As part of its continuing effort to reduce paperwork and respondent burdens, Interior invites the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps Interior assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand Interior's information collection requirements and provide the requested data in the desired format.

Interior is especially interested in public comment concerning:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of the estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. Interior will include or summarize each comment in its request to the OMB to approve this information collection request. Before commenters include their respective addresses, phone numbers, email addresses, or other personal identifying information in their comments, they should be aware that entire comments—including any personally identifying information—may be made publicly available at any time. While a commenter may request that personal identifying information be withheld from public review, Interior cannot guarantee that it will be able to do so.

Abstract: Infrastructure Investment and Jobs Act (Pub. L. 117–58) (November 15, 2021), section 40601, ''*Orphaned well site plugging, remediation, and restoration,*'' which is also known as the Bipartisan Infrastructure Law (BIL), amends section 349 of the Energy Policy Act of 2005 (42 U.S.C. 15907). Section 40601 designates Interior as the key agency responsible for implementing grant and other financial assistance programs for applicable government entities to plug, remediate, and reclaim orphaned wells on lands covered by the BIL. The associated investments will rebuild America's critical infrastructure, tackle the climate crisis, advance environmental justice, and drive the creation of good-paying union jobs.

Interior will issue financial assistance through grant awards to State and Tribal governments under Assistance Listing (CFDA) program 15.018 Energy Community Revitalization Program (ECRP). With respect to Tribal In Lieu of Grant Assistance, OWPO will coordinate with the Bureau of Indian Affairs. The authority for the above assistance is the Infrastructure Investment and Jobs Act, Division D, Title VI, Section 40601.

The types of assistance contained in section 40601 are as follows:

1. Initial Grants to States
2. Formula Grants to States
3. Performance Grants to States, which includes:
   - Regulatory Improvement Grants to States
   - Matching Grants to States
4. Grants to Tribes and Tribal In Lieu of Grant Assistance

The BIL requires Interior to collect information necessary to ensure that awarded grant and other assistance funds authorized by this legislation are used in accordance with the BIL, Federal assistance requirements (*i.e.,* 2 CFR part 200), and other applicable Federal law and authorities. Interior anticipates that most of the information will be collected by the OWPO, which has and will issue guidance concerning the above assistance programs. Interior seeks OMB approval of the proposed information collection to manage and monitor financial assistance applications and awards to ensure that States and Tribes comply with the BIL, 2 CFR part 200, and other applicable Federal law and authorities.

Consolidated Workplan

Interior proposes to collect the following from all State and Tribal grant applicants, unless noted otherwise, as part of each entity's consolidated workplan:

(a) An applicant's process for determining a well has been orphaned, including what efforts will be made to redeem financial assurances or otherwise recoup remediation costs from any responsible parties;

(b) A description of an applicant's plugging standards, including the witnessing requirements (*e.g.,* qualifications of witness, documentation);

(c) An applicant's prioritization process for evaluating and ranking orphan wells and associated surface reclamation, including criteria, weighting, and how such prioritization will address resource and financial risk, public health and safety, potential environmental harm (including methane emissions where applicable), and other land use priorities;

(d) If no prioritization process currently exists, an applicant's description of its plans to develop and implement a prioritization process;

(e) Details of how a State applicant will identify and address any disproportionate burden of adverse human health or environmental effects of orphaned wells on disadvantaged communities, low-income communities, and Tribal and indigenous communities;

(f) How applicants will identify and incorporate into their work plans health, safety, habitat, and environmental benefits of plugging, remediating, or reclamation of orphaned wells (Proposed revision);

(g) The methodology to be used by the applicant to measure and track methane and other gases associated with orphaned wells, including how the applicant will confirm the effectiveness of plugging activities in reducing or eliminating such emissions;

(h) The methodology to be used by the applicant to measure and track contamination of groundwater and surface water associated with orphaned wells, including how the applicant will confirm the effectiveness of plugging activities in reducing or eliminating such contamination;

(i) The methodology to be used to decommission or remove associated pipelines, facilities, and infrastructure and to remediate soil and restore habitat that has been degraded due to the presence of orphaned wells and associated infrastructure;

(j) Methods the applicant will use to solicit recommendations from local officials and the public regarding the prioritization of well plugging and site remediation activities, and any other processes the applicant will use to solicit feedback on the program from local officials and the public;

(k) Latitude/Longitude and all other data elements and associated units of measure as indicated in State and Tribal data reporting templates. *See* the *Data Associated with Wells Plugged Using Federal BIL Funds* portion of this proposed information collection;

(l) How the applicant will use funding to locate currently undocumented orphaned wells;

(m) Plans the applicant has to engage third parties in partnerships around well plugging and site remediation, or any existing similar partnerships the applicant currently belongs to;

(n) Training programs, registered apprenticeships, and local and economic hire agreements for workers the applicant intends to conduct or fund in well plugging or site remediation;

(o) Plans the applicant has to support opportunities for all workers, including workers underrepresented in well plugging or site remediation, to be trained and placed in good-paying jobs directly related to the project;

(p) For State applicants, plans the State applicant has to incorporate equity for underserved communities into their planning, including supporting the expansion of high-quality, good paying jobs through workforce development programs and incorporating workforce strategy into project development;

(q) Procedures the applicant will use to coordinate with Federal, State, or Tribal agencies to determine whether efficiencies may exist by combining field survey, plugging, or surface remediation work across lands covered by the BIL;

(r) The applicant's authorities to enter private property, or an applicant's procedures to obtain landowner consent to enter private property, in the event that any wells to be plugged will be accessed from privately owned surface;

(s) A work schedule covering the period of performance for the grant;

(t) If applicable, a federally approved Indirect Cost Rate Agreement or statement regarding applicant's intention to negotiate or utilize the de minimis rate;

(u) How an applicant will assist Interior to ensure that activities funded by the grant it applied for will comply with relevant Federal law and authorities, such as the Endangered Species Act of 1973, as amended (ESA), and the National Historic Preservation Act, as amended (NHPA) (Proposed revision);

(v) For Performance Grants, how a State applicant will place a higher priority on the use of the Federal funds to lower unemployment in the State, including workforce development activities related to orphaned well plugging, remediation, and reclamation (Proposed revision); and

(w) For Performance Grants, how a State applicant will place a higher priority on the use of the Federal funds to improve economic conditions in economically distressed areas of the State, provided the use of the funds is related to orphaned well plugging, remediation, and reclamation (Proposed revision).

Regulatory Improvement Grants—State Applicants Only

(Proposed Revision)

Under Section 40601(c)(5)(E)(i), a Regulatory Improvement Grant (RIG) may be awarded to an eligible State if either: (1) ''The State has strengthened plugging standards and procedures designed to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment'' (Plugging Standards RIG); or (2) ''The State has made improvements to State programs designed to reduce future orphaned well burdens, such as financial assurance reform, alternative funding mechanisms for orphaned well programs, and reforms to programs relating to well transfer or temporary abandonment'' (Program Standards RIG). In addition to a consolidated workplan, and other information required from RIG applicants that is discussed in this proposed information collection, Interior proposes to collect the following from applicants.

Plugging Standards RIGs: Interior proposes to collect from Plugging Standards RIG applicants information pertaining to their statutes, regulations, policies, and procedures, which were implemented during the 10-year period specified in the BIL, that demonstrate the ''State has strengthened plugging standards and procedures designed to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.'' The list, (a) through (j), below, are examples of information Interior proposes to collect. In determining whether a ''State has strengthened plugging standards and procedures,'' Interior may request additional types of information.

(a) Drilling well construction, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(b) Allowable well control equipment to manage actions of perforating, cutting/pulling of casing, or retrieving seal assemblies, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an

effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(c) Allowable barrier types, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(d) Allowable barrier placement locations, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(e) Allowable barrier placement techniques, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(f) Wellbore integrity and barrier verification, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(g) Spacer medium between well barriers, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(h) Wellbore capping requirements, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(i) Plugging procedure approval requirements, plugging procedure changes, plugging operations notification requirements, post-plugging reporting requirements, alternative materials or methods, and the resulting actual or anticipated positive effects of these changes, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

(j) Internal inspection and oversight, and long-term monitoring of plugged wells processes, and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to ensure that wells located in the State are plugged in an effective manner that protects groundwater and other natural resources, public health and safety, and the environment.

For Program Standards RIGs: Interior proposes to collect from Program Standards RIG applicants information pertaining to their statutes, regulations, policies, and procedures, which were implemented during the 10-year period specified in the BIL, that demonstrate the ''State has made improvements to State programs designed to reduce future orphaned well burdens, such as financial assurance reform, alternative funding mechanisms for orphaned well programs, and reforms to programs relating to well transfer or temporary abandonment.'' The list, (a) through (g), below, are examples of information Interior proposes to collect. In determining whether a ''State has made improvements to State programs designed to reduce future orphaned well burdens,'' Interior may request additional types of information.

(a) Liable parties, scope of liability, and state access (*e.g.,* non-operator liable parties, predecessor in interest liability, and state targeting of liable parties through increased or enhanced enforcement), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens.

(b) Transfers of interest (*e.g.,* notice of transfer to state from transferor and transferee, state assessment of transferor and/or transferee, and transferor maintenance of assurance), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens.

(c) Financial Assurance (*e.g.,* bonding adjusted for field, well, or operator risks), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens, including considerations for idle, marginal, and producing wells.

(d) Non-assurance State financial protections and plugging incentives (*e.g.,* fees, taxes, penalties (including increased or enhanced enforcement), and incentives), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens, including considerations for idle, marginal, and producing wells.

(e) Reporting and public notice of orphaned or potentially orphaned wells (*e.g.,* reporting mechanisms, for responsible parties, online notice of aggregate financial assurance, and online notice of marginal, orphaned, and all other wells by responsible party), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens, including considerations for idle, marginal, and producing wells.

(f) Consideration for air, groundwater, and other natural resources, as well as public safety and environmental justice (*e.g.,* considerations for surface and groundwater or soil, including hazardous materials or other contamination, special considerations for oil and gas wells converted to water wells, and considerations for public safety and environmental justice), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens, including considerations for idle, marginal, and producing wells.

(g) Orphaned-wells-related internal and external workforce development (*e.g.,* State internal workforce enhancements, State contracting process, and oversight of State vendors, including certificate programs), and the resulting actual or anticipated positive effects, or documentation, that demonstrate the State's intent to reduce future orphaned well burdens.

For both Plugging Standards and Program Standards Applications: For all Plugging Standards and Program Standards RIG applicants, Interior also proposes to collect the following:

Scoring Template: A list of questions related to the specific type of RIG they are applying for in a scoring template (*e.g.,* ''Yes'' or ''No''). Applicants will also need to provide support for the scoring template that they submit.

Interior will use the requested information to determine grant eligibility, including eligible amount, and to ensure that program objectives are being met, evaluate the applicant's readiness to obligate grant funds, and evaluate the applicant's approach to execute grant objectives and the grant-funded work that will be monitored by Interior.

Grant Applications

Interior proposes to collect the following additional elements from applicants:

- *Standard forms (SF) from the SF–424 Series:* Applicants must submit the following SF–424 series of forms:
  - SF–424, Application for Federal Assistance;
  - SF–424A, Budget Information for Non-Construction Programs or SF–424C Budget Information for Construction Program, or both;
  - SF–424B, Assurances for Non-Construction Programs) or SF–424D Assurances for Construction Programs);
  - SF–428 Tangible Personal Property Report; and
  - SF–LLL, Disclosure of Lobbying Activities, when applicable).
- *Indirect Cost Statement:* If requesting reimbursement for indirect costs, all applicants must include in their application a statement regarding how they anticipate charging indirect costs.
- *Budget Narrative and/or Template:* Applicants must provide a narrative and/or template that describes and justifies, with sufficient detail, the requested budget items and costs, and provides a description of how the applicant determined its totals by cost category in their application (Proposed revision).
- *Negotiated Indirect Cost Rate Agreement (NICRA):* When applicable, a copy of the applicant's current federal-agency-approved Negotiated Indirect Cost Rate Agreement is required.
- *Single Audit Reporting Statement:* All U.S. governmental entities and non-profit applicants must submit a statement regarding their single audit reporting status.
- *Conflict of Interest Disclosures:* Applicants must notify the Interior in writing of any actual or potential conflicts of interest known at the time of application or that may arise during the life of this award, in the event the Interior makes an award to the entity.
- *Certification Statement:* State applicants for the Initial Grant part of this program must provide a signed State Certification statement consistent with Section 40601(c)(3)(A)(ii)(III) or 40601(c)(3)(A)(i)(II) of the BIL. State and Tribal Applicants may also be required to submit other certifications for other grant programs, consistent with guidance issued by the OWPO.

Tribal In Lieu of Grant Assistance Requests—Tribal Applicants Only

(Proposed Revision)

Tribes, in lieu of grant assistance, may request that Interior administer and carry out plugging, remediation, and reclamation activities related to eligible orphaned wells on behalf of the Tribe. Interior proposes to collect the following information to evaluate and administer such requests:

- A letter of request for assistance, from the Tribe, bearing the signature of the authorized representative of the Tribe's governing body;
- A description of activities (*e.g.,* plugging and abandonment, remediation, and/or reclamation) for which the Tribe is requesting assistance;
- A brief description of the Tribe's territories, including the number and locations of known orphan wells; and
- A summary of known supporting data or information, including existing inventories and assessments and environmental compliance documents.

Amendments

For many budget and program plan revisions, 2 CFR part 200 requires recipients submit revision requests to the Federal awarding agency in writing for prior approval. Interior reviews such requests received to determine the eligibility and allowability of new or revised activities and costs and approves certain items of cost.

Reporting/Recordkeeping Requirements

To ensure that activities funded by Section 40601 are consistent with the BIL, 2 CFR part 200, and other Federal law and authorities, Interior proposes to collect the following information from all grant and other funding recipients:

- *Financial Reports:* Recipients are required to submit all financial reports on the Standard Form 425, Federal Financial Report. Recipients must submit financial reports in accordance with 2 CFR part 200. The frequency of submission may vary but will typically be annually or semi-annually. Interior, however, may require submission of financial reports more frequently in certain circumstances, such as where more frequent reporting is necessary for the effective monitoring of the Federal award or could significantly affect program outcomes (Frequency is proposed revision).
- *Performance Reports:* Recipients must submit performance reports in accordance with 2 CFR part 200. This information is necessary for Interior to track accomplishments and performance-related data. Interior uses these reports to ensure that the recipient is accomplishing its work on schedule, and to identify any problems that the recipient may be experiencing in accomplishing the work. While the frequency of performance reporting may vary, recipients typically will be required to submit their performance reports annually or semi-annually. Interior, however, may require the submission of these reports more frequently in certain circumstance, such as where more frequent reporting is necessary for the effective monitoring of the Federal award or could significantly affect program outcomes (Frequency is proposed revision).

  Performance reports must include:
  - A comparison of actual accomplishments to the goals and objectives established for the reporting period, the results/findings, or both;
  - If the goals and objectives were not met, the reasons why, including analysis and explanation of cost overruns or high unit costs compared to the benefit received to reach an objective;
  - Performance trend data and analysis to be used by the awarding program to monitor and assess recipient and Federal awarding program performance;
  - Consolidated long-term work plan and accomplishments updates, when award is part of a large scale or long-term effort funded under multiple awards over time; and
  - Other information that Interior requires to track State and Tribal accomplishments, collect performance-related data, identify and risks and failure to achieve certain milestones, and is otherwise necessary to ensure that the State's or Tribe's actions comply with the relevant guidance issued by the OWPO (Proposed revision).
- *Final 15-month Report for State Initial Grants:* As required in the BIL, State recipients under the Initial Grants part of the program must submit a report no later than 15 months after the date on which the State receives the funds, describing the means by which the State used the funds in accordance with its application and certification, and including the reporting parameters described in this guidance.
- *Recordkeeping Requirements:* Recipients must retain financial records, supporting documents, statistical records, and all other records pertinent to a Federal award, per 2 CFR part 200 requirements.
- *Data Associated with Wells Plugged Using Federal BIL Funds:* Recipients must periodically provide data, which upon Interior's request, may include pictures, video, or other media, for any well plugged with BIL funds. This may include data associated with reclamation or restoration of land or infrastructure associated with a well (Proposed revision).

Upon request, but no more frequently than annually, recipients must submit requested information related to aggregate orphaned-well data (*e.g.,* the total number of documented orphaned wells located in a State, and the rationale for why the orphaned well inventory has increased or decreased during a certain time period). Interior will use this information to evaluate the effectiveness of the programs funded by the BIL.

- *Information Concerning State or Tribal Unmet Needs:* When requested, States and Tribes must submit requested information related to unmet needs for orphaned well plugging, the decommission or removal of the associated infrastructure, and the restoration and reclamation of the lands, surface water, ground water, or other natural resources that are impacted or potentially impacted. States or Tribes may also be required to provide information regarding employment and economically distressed areas, or environmental justice (Proposed revision).
- *Compliance with Environmental and Other Statutes:* Recipients must submit information to Interior to allow Interior to ensure that Federal BIL funds are utilized in a manner that is consistent applicable Federal law, such as the ESA and NHPA, and other authorities and policy (Proposed revision).
- *Change in RIG Eligibility (Scoring Template):* During the ten-year period that begins on the date of receipt of the grant funds, each RIG recipient must periodically (*e.g.,* annually) submit an updated Scoring Template. This submission will allow Interior to ensure that the State recipient is not required to reimburse Interior for all or a portion of its RIG for ''failure to maintain protections,'' under Section 40601(c)(5)(E)(iii). Recipients will also be required to submit documentation that supports any changes between the submitted Scoring Template and the one that was previously submitted (Proposed revision).
- Interior also proposes to rename the information collection from *Application Requirement for States to Apply for Orphaned Well Site Plugging, Remediation, and Restoration Grant Consideration* to *Application Requirements for States and Tribes to Apply for Orphaned Well Site Plugging, Remediation, and Restoration Funding Consideration, and Ongoing State and Tribal Reporting Requirements for Funding Recipients* (Proposed revision).

Title of Collection: Application Requirements for States and Tribes to Apply for Orphaned Well Site Plugging, Remediation, and Restoration Funding Consideration, and Ongoing State and Tribal Reporting Requirements for Funding Recipients.

OMB Control Number: 1093–0012.

Form Number: None.

Type of Review: Revision and extension of a currently approved collection.

Respondents/Affected Public: Up to 92 (27 State and 65 Tribal governments).

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion

Total Estimated Annual Non-hour Burden Cost: None.

Requirement	Average Number of Annual Respondents	Average Number of Responses Each	Average Number of Annual Responses	Average Completion Time per Response	Estimated Annual Burden Hours
Consolidated Workplan					
State Government	27	1	27	10	270
Tribal Government	65	1	65	8	520
Grant Applications					
State and Tribal Government	92	1	92	40	3,680
Amendments					
State and Tribal Government	10	1	10	3	30
Financial Reports and Unmet Burdens (State and Tribal Governments)					
Reporting	92	1	92	6	552
Recordkeeping				2	184
Performance Reports (State Government)					
Reporting	27	1	27	32	864
Recordkeeping				2	54
Performance Reports (Tribal Government)					
Reporting	65	1	65	10	650
Recordkeeping				2	130
Final 15-Month Reports (State Government)					
Reporting	8	1	8	24	192
Recordkeeping				2	16
Compliance with Environmental and Other Statutes as Authorized					
State and Tribal Government	92	4	368	4	1,472
Totals:	***478***		***754***		***8,614***

Additional burden estimates for this revision request (*see* three tables below)

One-Time Burden Estimates

Requirement	Average Number of one-time Respondents	Average Number of Responses Each	Average Number of Annual Responses	Average Completion Time per Response, Hours	Estimated One-time Burden Hours
Regulatory Improvement Grant Eligibility					
State Government	27	2	54	24	1296
Scoring Template					
State Government	27	2	54	1	54
Totals:	***54***		***108***		***1,350***

Annual Burden Estimates

Requirement	Average Number of Annual Respondents	Average Number of Responses Each	Average Number of Annual Responses	Average Completion Time per Response, Hours	Estimated Annual Burden Hours
Scoring Template					
State Government	27	2	54	1	54
Totals:	***27***		***54***		***54***

Non-Grant Related Burden Estimates

Requirement	Average Number of Respondents	Average Number of Responses Each	Average Number of Responses	Average Completion Time per Response	Estimated Burden Hours
Tribal in Lieu of Grant Assistance					
Tribal Government	3	1	3	8	24
Totals:	**3**		**3**		**24**

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act and 5 CFR 1320.8(d)(1).

Jeffrey Parrillo,

Departmental Information Collection Clearance Officer.

[FR Doc. 2024–09525 Filed 5–1–24; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO4500169700.WYW106272479, WYW–165445]

Notice of Intent To Amend the Worland Resource Management Plan and Prepare an Associated Environmental Assessment; Notice of Realty Action: Proposed Non-Competitive Direct Sale of 1.0 Acre of Public Lands in Washakie County, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent; notice of realty action.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Wyoming State Director intends to prepare a Resource Management Plan (RMP) amendment with an associated Environmental Assessment (EA) for the non-competitive direct sale of public lands in Washakie County, Wyoming, and by this notice is announcing the beginning of the scoping period to solicit public comments and identify issues; providing the planning criteria for public review; and announcing a comment period on the proposed realty action offering a one-acre parcel of public lands by direct sale to TAG Western Properties, LLC for not less than the fair market value of $1,020.00.

DATES: The BLM requests that the public submit comments concerning the scope of the analysis, potential alternatives, identification of relevant information and studies, classification of the land for disposal, and the proposed direct sale by June 17, 2024. To afford the BLM the opportunity to consider issues raised by commenters in the Draft RMP/EA, please ensure your comments are received prior to the close of the 45-day scoping period or 15 days after the last public meeting, whichever is later.

ADDRESSES: You may submit comments on issues and planning criteria related to the proposed RMP amendment and non-competitive direct sale of public land in the Washakie County, Wyoming, by any of the following methods:

- Website: *https://eplanning.blm.gov/eplanning-ui/project/2023383/510*
- *Email: BLM_WY_Worland_WYMail@blm.gov*
- *Mail:* Field Manager, BLM, Worland Field Office, 101 South 23rd Street, Worland, WY 82401

Documents pertinent to this proposal may be examined online at the website above and at the Worland Field Office.

FOR FURTHER INFORMATION CONTACT: Connie Craft, Realty Specialist, telephone (307) 347–5233; address Worland Field Office, 101 South 23rd Street, Worland, WY 82401; email *c75craft@blm.gov*. Contact Ms. Craft to have your name added to our mailing list. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Wyoming State Director intends to prepare an RMP amendment with an associated EA for the non-competitive direct sale of public land in Washakie County, Wyoming; announces the

beginning of the scoping process; and seeks public input on issues and planning criteria. The RMP amendment is being considered to allow the BLM to evaluate the disposal of public lands to TAG Western Properties, LLC. The direct sale would be consistent with provisions of section 203 of FLPMA and BLM land-sale regulations at 43 CFR 2710. Publication of this notice in the **Federal Register** segregates the subject land from all forms of appropriation under the public land laws, including the general mining laws, and from the mineral leasing and geothermal leasing laws, except for the sale provisions of FLPMA. The planning area is in Washakie County, Wyoming, and encompasses 1.0 acre of public land.

The scope of this land use planning process does not include addressing the evaluation or designation of areas of critical environmental concern (ACECs), and the BLM is not considering ACEC nominations as part of this process.

Purpose and Need

The need of the proposed action is to resolve inadvertent, unauthorized development of public lands consisting of a metal shop and cabin constructed by a previous landowner, currently owned and operated by the proponent as an essential component of the adjoining ranch operations. The purpose for the proposed action is to convey lands from Federal ownership that are difficult and uneconomical to manage and are not suitable for management by another Federal department or agency (FLPMA, 43 U.S.C. 1713(a)(1)). The BLM proposes to amend the 2015 Worland RMP in conformance with section 203 of FLPMA, which requires that land made available for disposal under the sale authority be clearly identified in the relevant land use plan.

Preliminary Alternatives

The RMP identifies tracts of public land suitable for disposal; however, the subject land is not currently listed as available for disposal. The BLM will analyze the suitability of the 1.0 acre for disposal per the criteria listed in FLPMA Section 203(a). The RMP amendment would allow for the land to be sold if it is found suitable for disposal.

The BLM is considering a direct sale of the following described land:

Sixth Principal Meridian, Wyoming

Township 45 North, Range 87 West,
Sec. 30, Parcel A.

The area described contains 1.0 acre, according to the official plat of survey of said land on file with the BLM.

The conveyance document, if issued, will contain the following terms, covenants, conditions, and reservations:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States pursuant to the Act of August 30, 1890, (43 U.S.C. 945);

2. All the mineral deposits in the land so patented pursuant to the Act of October 21, 1976 (43 U.S.C. 1719), including, without limitation, substances subject to disposition under the general mining laws, the general mineral leasing laws, the Materials Act, and the Geothermal Steam Act, and to it, its permittees, licensees, lessees, and mining claimants, the right to prospect for, mine, and remove the minerals owned by the United States under applicable law and such regulations as the Secretary of the Interior may prescribe. This reservation includes necessary access and exit rights and the right to conduct all necessary and incidental activities including, without limitation, all drilling, underground, open pit or surface mining operations, storage, and transportation facilities deemed reasonably necessary.

Unless otherwise provided by separate agreement with the surface owner, mining claimants, permittees, licensees, and lessees of the United States shall reclaim disturbed areas to the extent prescribed by regulations issued by the Secretary of the Interior.

All causes of action brought to enforce the rights of the surface owner under the regulations above referred to shall be instituted against mining claimants, permittees, licensees, and lessees of the United States; and the United States shall not be liable for the acts or omissions of its mining claimants, permittees, licensees, and lessees.

3. An appropriate indemnification clause protecting the United States from claims arising out of the patentee's use, occupancy, or operations on the patented land.

The conveyance document, if issued, will be subject to all valid existing rights.

The No Action Alternative would not amend the 2015 Worland RMP to allow for the disposal of the tract if found to be suitable per the criteria listed in the FLPMA section 203(a). The tract would be retained in federal ownership and the BLM would proceed with a formal trespass action. Revenues to local taxing districts would not change. Additional actions would be considered by the BLM on a case-by-case basis.

The BLM welcomes comments on all preliminary alternatives as well as suggestions for additional alternatives.

Planning Criteria

The planning criteria guide the planning effort and lay the groundwork for effects analysis by identifying the preliminary issues and their analytical frameworks. Preliminary issues for the planning area have been identified by BLM personnel and from early engagement conducted for this planning effort with Federal, State, and local agencies; Tribes; and stakeholders. The BLM has identified wildlife as a preliminary issue for this planning effort's analysis. The planning criteria are available for public review and comment at the ePlanning website (see **ADDRESSES**).

Public Scoping Process

This notice of intent initiates the scoping period and public review of the planning criteria, which guide the development and analysis of the RMP Amendment and EA.

The BLM does not intend to hold any public meetings, in-person or virtual, during the public scoping period. Should the BLM later determine to hold public meetings, the specific date(s) and location(s) of any meeting will be announced at least 15 days in advance through announcements in the *Northern Wyoming News*.

Sale Notifications

The segregation will terminate upon issuance of a conveyance document or on May 2, 2026, whichever occurs first. The BLM is no longer accepting land-use applications affecting the subject public land, except applications to amend previously filed right-of-way applications or existing authorizations to increase grant terms in accordance with 43 CFR 2807.15 and 43 CFR 2886.15.

The notification of the proposed RMP amendment and EA and, if applicable, unsigned Finding of No Significant Impact (FONSI) will begin a 30-day protest period subject to BLM Manual Section 2711.1 step 4(d) on the land-sale decision. The BLM Wyoming State Director will review all protests and may sustain, vacate, or modify the RMP amendment and land sale, in whole or in part. In the absence of any protests and upon reaching a FONSI, the BLM will select the approved RMP amendment alternative and prepare a decision record which will document the final determination of the Department of the Interior for the land sale.

In addition to publication of this notice in the **Federal Register**, the BLM will publish this notice in the *Northern Wyoming News* once a week for three consecutive weeks.

Interdisciplinary Team

The BLM will use an interdisciplinary approach to develop the plan to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in this planning effort: outdoor recreation, archaeology, wildlife, lands and realty, minerals and geology, soils, vegetation, sociology, and economics.

Additional Information

The BLM will identify, analyze, and consider mitigation to address the reasonably foreseeable impacts to resources from the proposed plan amendment and all analyzed reasonable alternatives and, in accordance with 40 CFR 1502.14(e), include appropriate mitigation measures not already included in the proposed plan amendment or alternatives. Mitigation may include avoidance, minimization, rectification, reduction or elimination over time, and compensation, and may be considered at multiple scales, including the landscape scale.

The BLM will utilize and coordinate the NEPA and land use planning processes for this planning effort to help support compliance with applicable procedural requirements under the Endangered Species Act (16 U.S.C. 1536) and Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) as provided in 36 CFR 800.2(d)(3), including public involvement requirements of Section 106. The information about historic and cultural resources and threatened and endangered species within the area potentially affected by the proposed plan will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian Tribal Nations on a government-to-government basis in accordance with Executive Order 13175, BLM Manual Section 1780, and other Departmental policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with Indian Tribal Nations and other stakeholders that may be interested in or affected by the proposed RMP amendment and non-competitive direct sale of public land in Washakie County, Wyoming, that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

Before including your address, phone number, email address or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1501.9, 43 CFR 1610.2, and 43 CFR part 2710)

Andrew Archuleta,

State Director, BLM Wyoming.

[FR Doc. 2024–09540 Filed 5–1–24; 8:45 am]

BILLING CODE 4331–26–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NM_FRN_MO4500178720]

Notice of Protest Acceptance; Oklahoma

AGENCY: Bureau of Land Management, Interior.

ACTION: Protest decision accepted.

SUMMARY: On September 29, 2020, the Bureau of Land Management (BLM) published in the **Federal Register**, Volume 85, Number 189, on page 61028, a notice entitled ''Notice of Filing of Plats of Survey; New Mexico; Oklahoma.'' The Notice stated that four supplemental plats were scheduled to be officially filed 30 days after the date, unless a person or party who wished to protest any of these surveys filed a timely, written Notice of Protest. On October 23, 2020, the Bureau of Land Management received a timely protest to the filing of the four supplemental plats.

SUPPLEMENTARY INFORMATION: On September 14, 2021, the BLM published a notice in the **Federal Register**, Volume 86, Number 175, on page 51182, a notice entitled ''Notice of Filing of Plats of Survey; Oklahoma.'' This notice stated that the official filing of the four Oklahoma supplemental plats had been stayed, pending consideration of all protests.

On February 27, 2024, the BLM New Mexico State Office State Director issued a decision and accepted the Arkansas River Authority's protest of the four supplemental plats.

The previous notices and protest decision letter apply to the following Supplemental Plats:

Indian Meridian, Oklahoma

The supplemental plat, within Township 10 North, Range 27 East, section 4, accepted July 8, 2020, for Group 224, Oklahoma.

The supplemental plat, within Township 10 North, Range 27 East, section 5, accepted July 8, 2020, for Group 224, Oklahoma.

The supplemental plat, in two sheets, within Township 10 North, Range 27 East, section 19, accepted August 13, 2020, for Group 223, Oklahoma.

The supplemental plat, within Township 11 North, Range 27 East, section 33, accepted July 8, 2020, for Group 224, Oklahoma.

The stay of filing published in the **Federal Register** on September 14, 2021, will not be lifted because the protest was accepted, and the acceptance of the plats was cancelled.

Authority: 43 U.S.C. chap. 3.

Melanie G. Barnes,

BLM New Mexico State Director.

[FR Doc. 2024–09324 Filed 5–1–24; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500179376; AA–41952]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface and subsurface estates in certain lands to Cook Inlet Region, Inc., an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 and the Act of January 2, 1976.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Cameron Means, Land Law Examiner, BLM Alaska State Office, 907–271–3152, or *cmeans@blm.gov*. Individuals

in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Cook Inlet Region, Inc. The decision approves conveyance of the surface and subsurface estates in certain lands pursuant to ANCSA (43 U.S.C. 1601), and the Act of January 2, 1976 (43 U.S.C. 1611 note), as amended. The lands are located in the vicinity of Anchorage, Alaska, and are described as:

Seward Meridian, Alaska

T. 12 N., R. 5 W.,
Sec. 8.
Containing approximately 5 acres.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above.

The BLM will also publish notice of the decision once a week for four consecutive weeks in the ''Anchorage Daily News'' newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until June 3, 2024 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Cameron G. Means,

Land Law Examiner, Branch of Adjudication.

[FR Doc. 2024–09488 Filed 5–1–24; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–37690; PPWODIREP0; PPMPSAS1Y.000000; PX.XDIRE0039]

Notice of the June 10 and 11, 2024, Meeting of the Advisory Committee on Reconciliation in Place Names

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Advisory Committee on Reconciliation in Place Names (Committee) will meet as noted below.

DATES: The Committee will meet on Monday June 10, 2024, from 11 a.m. until 6 p.m. (MOUNTAIN) and Tuesday June 11, 2024, from 9 a.m. until 5:30 p.m. (MOUNTAIN). Individuals that wish to participate must contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than Friday May 31, 2024, to receive instructions for accessing the meeting.

ADDRESSES: The Committee will meet at The Outdoor Campus (West), 4130 Adventure Trail, Rapid City, SD 57702. Electronic submissions of materials or requests are to be sent to *reconciliation_committee@nps.gov.* The meeting will also be accessible virtually via webinar and audio conference technology.

FOR FURTHER INFORMATION CONTACT: For information concerning attending the Committee meeting in-person or virtually, submitting written comments to the Committee, or requesting to address the Committee, contact the Office of Policy, National Park Service, at *reconciliation_committee@nps.gov* or by telephone at (202) 354–3950.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Committee has been established by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906 and is regulated by the Federal Advisory Committee Act.

Purpose of the Meeting: The Committee will present its work identifying Federal land unit and geographic feature names that may be considered derogatory, and its recommendations for determining a process to engage Tribes, State and local governments, affected Federal agencies, and members of the public in identifying additional derogatory terms and Federal land unit and geographic feature names. The final agenda and briefing materials will be posted to the Committee's website prior to the meeting at *https://www.nps.gov/orgs/1892/advisory-committee-on-reconciliation-in-place-names.htm.*

The meeting is open to the public. Interested persons may choose to make oral comments at the meeting during the designated time for this purpose. Depending on the number of people wishing to comment and the time available, the amount of time for oral comments may be limited. Interested parties should contact the National Park Service Office of Policy (see **FOR FURTHER INFORMATION CONTACT**) for advance placement on the public speaker list for this meeting. Members of the public may also choose to submit written comments by emailing them to *reconciliation_committee@nps.gov.* Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record. All comments will be made part of the public record and will be electronically distributed to all Committee members. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Meeting Accessibility: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2024–09515 Filed 5–1–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–37691; PPWOCRADN0–PCU00RP16.R50000]

Native American Graves Protection and Repatriation Review Committee Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service is hereby giving notice that the Native American Graves Protection and Repatriation Review Committee (Committee) will hold a virtual meeting as indicated below.

DATES: The Committee will meet via teleconference on Thursday, May 23, 2024, from 2:00 p.m. until approximately 6:00 p.m. (Eastern). The meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Melanie O'Brien, Designated Federal Officer, National Native American Graves Protection and Repatriation Act Program (2253), National Park Service, telephone (202) 354–2201, or email *nagpra_info@nps.gov.*

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Committee was established in section 8 of the Native American Graves Protection and Repatriation Act of 1990 (NAGPRA). Information about NAGPRA, the Committee, and Committee meetings is available on the National NAGPRA Program website at *https://www.nps.gov/subjects/nagpra/review-committee.htm.*

The Committee is responsible for monitoring the NAGPRA inventory and identification process; reviewing and making findings related to the identity or cultural affiliation of cultural items, or the return of such items; facilitating the resolution of disputes; compiling an inventory of culturally unidentifiable human remains that are in the possession or control of each Federal agency and museum, and recommending specific actions for developing a process for disposition of such human remains; consulting with Indian Tribes and Native Hawaiian organizations and museums on matters affecting such Tribes or organizations lying within the scope of work of the Committee; consulting with the Secretary of the Interior on the development of regulations to carry out NAGPRA; and making recommendations regarding future care of repatriated cultural items. The Committee's work is carried out during the course of meetings that are open to the public.

The agenda for the meeting may include a report from the National NAGPRA Program; the discussion of the Review Committee Report to Congress; subcommittee reports and discussion; and other topics related to the Committee's responsibilities under section 8 of NAGPRA. In addition, the agenda may include presentations by Indian tribes, Native Hawaiian organizations, museums, Federal agencies, associations, and individuals, and public comment. The agenda and materials for this meeting will be posted on or before May 9, 2024, at *https://www.nps.gov/orgs/1335/events.htm.* Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

To submit a request or comment, see **FOR FURTHER INFORMATION CONTACT**. Information on joining the meeting by internet or telephone will be available on the National NAGPRA Program website at *https://www.nps.gov/orgs/1335/events.htm.*

Meeting Accessibility: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Before including your address, telephone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10; 25 U.S.C. 3006.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2024–09514 Filed 5–1–24; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–24–016]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: May 9, 2024 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. 731–TA–1675–1678 (Preliminary) (Dioctyl Terephthalate (DOTP) from Malaysia, Poland, Taiwan, and Turkey). The Commission currently is scheduled to complete and file its determinations on May 10, 2024; views of the Commission currently are scheduled to be completed and filed on May 17, 2024.
5. Outstanding action jackets: none.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: April 29, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–09626 Filed 4–30–24; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–726 and 731–TA–1694 (Preliminary)]

High Chrome Cast Iron Grinding Media From India; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–726 and 731–TA–1694 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of high chrome cast iron grinding media from India, provided for in subheading 7325.91.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of India. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by June 10, 2024. The Commission's views must be transmitted to Commerce within five business days thereafter, or by June 17, 2024.

DATES: April 26, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Stebbins, (202) 205–2039, Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on April 26, 2024, by Magotteaux Inc., Franklin, Tennessee.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on Friday, May 17, 2024. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before Wednesday, May 15, 2024. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on May 22, 2024, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than noon on May 16, 2024. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or

reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: April 26, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–09509 Filed 5–1–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Modification

On April 24, 2024, the Department of Justice lodged a proposed Consent Decree Modification (''Modification'') with the United States District Court for the Eastern District of Michigan in the lawsuit entitled *United States* v. *Dow Silicones Corp.* Civ. A. No. 19–11880.

The proposed Modification amends the Revised Consent Decree entered by the Court on January 24, 2020, which resolved Plaintiff's claims that Defendant violated various federal environmental statutes including the Clean Water Act at its chemical manufacturing plant located in Midland, Michigan. The proposed Modification extends a deadline in the Revised Consent Decree for Defendant's implementation of a Stormwater Capacity and Pollutant Evaluation from January 24, 2023 to January 24, 2026. The proposed Modification also includes requirements to mitigate any environmental harm associated with the extension of the deadline.

The publication of this notice opens a period for public comment on the proposed Modification. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Dow Silicones Corp.* Civ. A. No. 19–11880 and DJ No. 90–5–2–1–10469. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Modification may be examined and downloaded at this Justice Department website: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* If you require assistance accessing the proposed Modification, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Laura Thoms,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–09547 Filed 5–1–24; 8:45 am]

BILLING CODE 4410–15–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Strategy hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, May 8, from 11:00 a.m.–12:00 p.m. Eastern.

PLACE: This meeting will be via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Chair's Opening Remarks about the Agenda; Long term Planning and FY 2026 Budget Development.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2024–09634 Filed 4–30–24; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–445 and 50–446; NRC–2022–0183]

Vistra Operations Company, LLC.; Luminant; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Final Supplemental Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has published a final plant-specific supplement, Supplement 60, License Renewal, to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants, NUREG–1437, regarding the renewal of Facility Operating License Nos. NPF–87 and NPF–89 for an additional 20 years of operation for Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2, respectively (CPNPP). CPNPP is located in Somervell County, Texas.

DATES: The final Supplement 60, License Renewal to the GEIS is available on May 2, 2024.

ADDRESSES: Please refer to Docket ID NRC–2022–0183 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2022–0183. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The final Supplement 60, License Renewal is available in ADAMS under Accession No. ML24078A261.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an

appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

• *Public Library:* A copy of Supplement 60, License Renewal, to the GEIS for License Renewal of Nuclear Plants, NUREG–1437, will be available at the following locations: Somervell County Library, 108 Allen Dr., Glen Rose, TX 76043 and Hood County Library, 222 N Travis St., Granbury, TX 76048.

The NRC staff encourages those addressees with mailing addresses listed in Chapter 7 of the final Supplemental Environmental Impact Statement, to visit the NRC's NUREG-Series Publication website (*https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff.html*) or the CPNPP project website (*https://www.nrc.gov/reactors/operating/licensing/renewal/applications/comanche-peak.html*) to download an electronic copy. You may also obtain an electronic copy by contacting Tam Tran via email at *Tam.Tran@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Tam Tran, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3617, email: *Tam.Tran@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 51.118 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Final environmental impact statement—notice of availability,'' the NRC is making available final Supplement 60, License Renewal to NUREG–1437, regarding the renewal of Vistra Operations Company LLC; Luminant (Vistra), operating licenses NPF–87 and NPF–89 for an additional 20 years of operation for CPNPP. A Notice of Availability of draft Supplement 60, License Renewal to NUREG–1437 was published in the **Federal Register** on November 9, 2023 (88 FR 77308), by the Environmental Protection Agency. The public comment period on draft Supplement 60, License Renewal to NUREG–1437 ended on December 26, 2023, and the comments received are addressed in final Supplement 60, License Renewal to NUREG–1437.

II. Discussion

As discussed in Chapter 4 of final Supplement 60, License Renewal to NUREG–1437, the NRC staff determined that the adverse environmental impacts of subsequent license renewal for CPNPP are not so great that preserving the option of subsequent license renewal for energy-planning decisionmakers would not be unreasonable. This recommendation is based on: (1) the analysis and findings in the GEIS; (2) information provided in the environmental report and other documents submitted by Vistra; (3) consultation with Federal, State, Tribal, and local agencies; (4) the NRC staff's independent environmental review; and (5) consideration of public comments received during the scoping process and on the draft SEIS.

Dated: April 26, 2024.

For the Nuclear Regulatory Commission.

John M. Moses,

Deputy Director, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–09486 Filed 5–1–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–18, 50–70, 50–73, 50–183, and 70–754; NRC–2023–0191]

In the Matter of GE-Hitachi Nuclear Energy Americas, LLC and NorthStar Vallecitos, LLC; Vallecitos Nuclear Center; Direct Transfer of Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an order approving the license transfer application filed by GE-Hitachi Nuclear Energy Americas, LLC (GEHA) and NorthStar Vallecitos, LLC (NorthStar Vallecitos), dated September 1, 2023, as supplemented by letters dated September 5, 2023, October 19, 2023, November 1, 2023, January 22, 2024, and March 15, 2024. Specifically, the order approves the direct transfer of control of Possession Only License Nos. DPR–1 for the Vallecitos Boiling Water Reactor, TR–1 for the General Electric Test Reactor, R–33 for the Nuclear Test Reactor, and DR–10 for the Empire State Atomic Development Associates Experimental Vallecitos Superheat Reactor and Special Nuclear Material (SNM) License No. SNM–960 from GEHA to NorthStar Vallecitos and the issuance of conforming amendments to the licenses, including license conditions.

DATES: The order was issued on April 25, 2024, and is effective for 1 year.

ADDRESSES: Please refer to Docket ID NRC–2023–0191 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0191. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov*. The order, the NRC staff safety evaluation supporting the order, and the draft conforming license amendments are available in ADAMS under Package Accession No. ML24039A011.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chris Allen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6877; email: *William.Allen@nrc.gov*.

SUPPLEMENTARY INFORMATION: The text of the order is attached.

Dated: April 26, 2024.

For the Nuclear Regulatory Commission.

William Allen,

Project Manager, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

Attachment—Order Approving Transfer of Licenses and Conforming License Amendments

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

In the Matter of: GE-Hitachi Nuclear Energy Americas, LLC, Vallecitos Nuclear Center 50–183, EA–24–040 DR–10, Docket Nos.: 50–18, 50–70, 50–73, and 70–754, License Nos.: DPR–1, TR–1, R–33, and SNM–960.

Order Approving Transfer of Licenses and Conforming License Amendments

I.

GE-Hitachi Nuclear Energy Americas, LLC (GEHA) is the holder of Possession Only License No. DPR–1 for the Vallecitos Boiling Water Reactor, Possession Only License No. TR–1 for the General Electric Test Reactor, Possession Only License No. R–33 for the Nuclear Test Reactor, and Possession Only License No. DR–10 for the Empire State Atomic Development Associates Experimental Vallecitos Superheat Reactor. These licenses authorize GEHA to possess the nuclear material associated with each reactor license subject to the conditions specified therein. They do not authorize GEHA either to use or to operate the reactors associated with the licenses. These reactor facilities are located at the Vallecitos Nuclear Center (VNC) in Sunol, California. GEHA is also the holder of Special Nuclear Material (SNM) License No. SNM–960, which authorizes the storage of SNM at the VNC.

II.

By application dated September 1, 2023 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML23244A247), as supplemented by letters dated September 5, 2023 (ML23248A232); October 19, 2023 (ML23292A336); November 1, 2023 (ML23305A052); January 22, 2024 (ML24022A323); and March 15, 2024 (ML24075A277), GEHA and NorthStar Vallecitos, LLC (NorthStar Vallecitos) (collectively, the Applicants) requested that the U.S. Nuclear Regulatory Commission (NRC) consent to the direct transfer of control of Possession Only License No. DPR–1 for the Vallecitos Boiling Water Reactor, Possession Only License No. TR–1 for the General Electric Test Reactor, Possession Only License No. R–33 for the Nuclear Test Reactor, Possession Only License No. DR–10 for the Empire State Atomic Development Associates Experimental Vallecitos Superheat Reactor, and SNM License No. SNM–960 (collectively, the licenses) located at the VNC in Sunol, California. Specifically, the Applicants requested that the NRC consent to the direct transfer of GEHA's currently licensed authority to possess nuclear material, to maintain the VNC in a safe condition (including storage, control, and maintenance of all nuclear material), and to decommission the VNC to NorthStar Vallecitos. This license transfer application was submitted to the NRC for approval under Section 184, ''Inalienability of Licenses,'' of the Atomic Energy Act of 1954, as amended (AEA), and Title 10 of the *Code of Federal Regulations* (10 CFR) 50.80, ''Transfer of licenses''; 10 CFR 50.90, ''Application for amendment of license, construction permit, or early site permit''; 10 CFR 70.34, ''Amendment of licenses''; and 10 CFR 70.36, ''Inalienability of licenses.'' Notice of the receipt of the license transfer application and opportunity to comment, request a hearing, and petition for leave to intervene was published in the **Federal Register** on November 8, 2023 (88 FR 77113). The supplemental letters, listed above, contained clarifying information and did not expand the license transfer application beyond the scope of the original notice.

GEHA intends to transfer its licensed possession, maintenance, and decommissioning authorities to NorthStar Vallecitos to expedite the decommissioning at the VNC. Following approval and completion of the proposed direct transfer of control of the licenses, NorthStar Vallecitos would assume licensed responsibility for the VNC through the transfer of GEHA's responsibility for licensed activities at the VNC to NorthStar Vallecitos. NorthStar Vallecitos would own the VNC facility as well as its associated assets and real estate, including its decommissioning trust fund, title to spent nuclear fuel, and rights under the terms of its Standard Contract for Disposal of Spent Nuclear Fuel and/or High-Level Radioactive Waste with the U.S. Department of Energy. Upon the proposed license transfer, NorthStar Vallecitos would assume responsibility for compliance with the current licensing basis, including regulatory commitments that exist at the closing of the transfer transaction between the Applicants, and would implement any changes under applicable regulatory requirements and practices. The Applicants also requested that the NRC impose license conditions relating to the management of the decommissioning trust fund, established for the purpose of providing decommissioning financial assurance for the licenses, and approve conforming administrative amendments to the licenses to reflect the direct transfer of the licenses from GEHA to NorthStar Vallecitos.

The NRC received one public comment on the license transfer application. It is summarized in the NRC staff's safety evaluation of the license transfer application. The NRC staff reviewed the comment submission and considered it, as appropriate, as part of its evaluation of the application.

Under 10 CFR 50.80, no license for a production or utilization facility, or any right thereunder, shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. Under 10 CFR 70.36, no license to possess or use special nuclear material, or any right thereunder, shall be transferred, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing. Upon review of the information in the license transfer application, as supplemented, and other information before the Commission, and relying upon the representations and agreements contained in the application, the NRC staff has determined that NorthStar Vallecitos is qualified to be the holder of the licenses, and that the direct transfer of the licenses, as described in the application, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto, subject to the condition set forth below.

Upon review of the request in the license transfer application, as supplemented, for conforming administrative amendments to the licenses to reflect the direct transfer of the licenses, the NRC staff has determined the following:

(1) The application for amendments complies with the standards and requirements of the AEA and the Commission's rules and regulations set forth in 10 CFR Chapter I.

(2) There is reasonable assurance that the activities authorized by the amendments can be conducted without endangering the health and safety of the public and that such activities will be

conducted in compliance with the Commission's regulations.

(3) The issuance of the amendments will not be inimical to the common defense and security or to the health and safety of the public.

(4) The issuance of the amendments is in accordance with 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' of the Commission's regulations, and all applicable requirements have been satisfied.

The findings set forth above are supported by an NRC staff safety evaluation dated April 25 2024, which is available at ML24039A011.

III.

Accordingly, under Sections 161b, 161i, 161o, and 184 of the AEA; 42 U.S.C. 2201(b), 2201(i), 2201(o), and 2234; and 10 CFR 50.80, 10 CFR 50.90, 10 CFR 70.34, and 10 CFR 70.36, IT IS HEREBY ORDERED that the application for the direct transfer of the licenses from GEHA to NorthStar Vallecitos, as described herein, is approved subject to the following condition:

Prior to the closing of the license transfer transaction, NorthStar Vallecitos, LLC shall provide the Director of the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) satisfactory documentary evidence that it has obtained, or will have obtained upon the closing of the transaction, the appropriate amount of insurance under 10 CFR part 140 and 10 CFR 50.54(w), as applicable.

It is further ordered that, consistent with 10 CFR 2.1315(b), the license amendments that make changes, as indicated in Enclosures 2 through 7 to the letter transmitting this Order, to reflect the subject direct license transfer are approved. The amendments shall be issued and made effective at the time the license transfer transaction is completed.

It is further ordered that NorthStar Vallecitos shall, at least 2 business days before the planned closing of the license transfer transaction, inform the Director of NMSS in writing of the planned closing date. Should the proposed transfer not be completed within 1 year of this Order's date of issuance, this Order shall become null and void; provided, however, that upon written application and for good cause shown, such date may be extended by order. The condition of this Order may be amended upon application by the Applicants and approval by the NRC.

This Order is effective upon issuance.

For further details with respect to this Order, see the license transfer application dated September 1, 2023, as supplemented on September 5, 2023; October 19, 2023; November 1, 2023; January 22, 2024; and March 15, 2024, and the associated NRC staff safety evaluation dated April 25 2024, which are available for public inspection at the Commission's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Publicly available documents are accessible electronically through ADAMS in the NRC Library at *https://www.nrc.gov/reading-rm/adams.html.* Persons who encounter problems with ADAMS should contact the NRC's PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737 or by email to *PDR.Resource@nrc.gov*.

Dated: April 25, 2024.

For The Nuclear Regulatory Commission.

/RA/

John W. Lubinski, Director,

Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–09487 Filed 5–1–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 24, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 61 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–248, CP2024–254.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09493 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 22, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 59 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–244, CP2024–250.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09491 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 22, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 226 to Competitive Product List.* Documents

are available at *www.prc.gov,* Docket Nos. MC2024–247, CP2024–253.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09497 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 228 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–253, CP2024–259.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09499 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 227 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–250, CP2024–256.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09498 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 22, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 225 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–245, CP2024–251.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09496 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 62 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–251, CP2024–257.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09495 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail, USPS Ground Advantage® & Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail, USPS Ground Advantage® & Parcel Select Contract 6 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–252, CP2024–258.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09490 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 229 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–254, CP2024–260.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09500 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 26, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 230 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–255, CP2024–261.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09501 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 24, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 62 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–249, CP2024–255.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09494 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 2, 2024.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on April 22, 2024, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 60 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2024–246, CP2024–252.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2024–09492 Filed 5–1–24; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100038; File No. SR–CboeBZX–2024–006]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend Rule 11.9(c)(6) and Rule 11.13(a)(4)(D) To Permit the Use of BZX Post Only Orders at Prices Below $1.00

April 26, 2024.

I. Introduction

On January 8, 2024, Cboe BZX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit the use of BZX Post Only Orders at prices below $1.00. The proposed rule change was published for comment in the **Federal Register** on January 29, 2024.[3] On March 8, 2024, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission did not receive any comments. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change [7]

The Exchange proposes to amend Rule 11.9(c)(6) and Rule 11.13(a)(4)(D)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99414 (January 23, 2024), 89 FR 5596 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 99698, 89 FR 18694 (March 14, 2024) (designating April 26, 2024, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] For a more detailed description of the proposed rule change, including examples, refer to the Notice, *supra* note 3.

to modify the treatment of BZX Post Only Orders priced below a dollar on the Exchange. BZX Post Only Orders priced at or above $1.00 will only remove liquidity if the value of the execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the BZX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. Currently, all BZX Post Only Orders priced below $1.00 are automatically treated as orders that remove liquidity. Under the proposed rule change, BZX Post Only Orders priced below $1.00 will be treated in the same manner as BZX Post Only Orders priced at or above $1.00 in that BZX Post Only Orders priced below $1.00 will only remove liquidity if the value of the overall execution (taking into account all applicable fees and rebates) make it economically beneficial for the order to remove liquidity.

The Exchange also proposes to amend Rule 11.13(a)(4)(D) to permit Non-Displayed Orders [8] and orders subject to display-price sliding (collectively, ''Resting Orders'') which are not executable at their most aggressive price due to the presence of a contra-side BZX Post Only Order to be executed at one minimum price variation less aggressive than the order's most aggressive price.[9]

Currently, Rule 11.13(a)(4)(D) states that, for securities priced above $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at, in the case of an incoming sell order, one-half minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one-half minimum price variation more than the price of the displayed order. The Exchange proposes that for securities priced below $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at, in the case of an incoming sell order, one minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one minimum price variation more than the price of the displayed order.

III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBZX–2024–006, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [10] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[11] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to permit the use of BZX Post Only Orders at prices below $1.00. In addition, as described above, for securities priced below $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at one minimum price variation less (more) than the price of the displayed order for sell (buy) orders.[12] In contrast, under the current rule for securities priced above $1.00, the incoming order would execute at one-half minimum price variation less (more) than the price of the displayed order for sell (buy) orders.[13] The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[14] In addition, Sections 6(b)(5) and 6(b)(8) of the Act, respectively, prohibit the rules of an exchange from being designed to permit unfair discrimination between customers, issuers, brokers, or dealers [15] or imposing any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[16]

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.'' [17] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[18] and any failure of a self-regulatory organization to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[19]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to

[8] *See* Rule 11.9(c)(11). A ''Non-Displayed Order'' is a market or limit order that is not displayed on the Exchange.

[9] *See* Securities Exchange Act Release No. 64475 (May 12, 2011), 76 FR 28830 (May 18, 2011), SR–BATS–2011–015 (''Resting Order Execution Filing''). The Resting Order Execution Filing introduced an order handling change for certain Non-Displayed Orders and orders subject to display-price sliding that are not executable at prices equal to displayed orders on the opposite side of the market (the ''locking price''). The Resting Order Execution Filing permits Resting Orders priced at or above $1.00 to be executed at one-half minimum price variation less aggressive than the locking price (for bids) and one-half minimum price variation more aggressive than the locking price (for offers), under certain circumstances.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] *Id.*

[12] According to the Exchange, executing an incoming order at the same price as the price as that of a displayed order on the same side of the market would violate the time priority of the displayed order. *See* Notice *supra* note 3, 89 FR at 5599; *see also* Exchange Rules 11.12(a) and 11.13(a)(4).

[13] *See* Exchange Rule 11.13(a)(4)(D).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(8).

[17] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[18] *See id.*

[19] *See id.*

Rule 19b–4 under the Act,[20] any request for an opportunity to make an oral presentation.[21]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by May 23, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 6, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–006 and should be submitted by May 23, 2024. Rebuttal comments should be submitted by June 6, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09472 Filed 5–1–24; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 240.19b–4.

[21] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[22] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100041; File No. SR–MIAX–2024–25]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Increase Fees for the ToM Market Data Product and Establish Fees for the cToM Market Data Product

April 26, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 23, 2024, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Fee Schedule (''Fee Schedule'') to: (i) amend the fees for the MIAX Top of Market (''ToM'') data feed; and (ii) establish fees for the MIAX Complex Top of Market (''cToM'') data feed. The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings*, at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to: (i) amend the fees for ToM; and (ii) establish fees for cToM. The ToM data feed contains top of book quotations based on options orders [3] and quotes [4] resting on the Exchange's Simple Order Book [5] as well as administrative messages.[6] The cToM data feed includes the same types of information as ToM, but for Complex Orders [7] on the Exchange's Strategy Book.[8] This information includes the Exchange's best bid and offer for a complex strategy,[9] with aggregate size,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''order'' means a firm commitment to buy or sell option contracts. *See* Exchange Rule 100.

[4] The term ''quote'' or ''quotation'' means a bid or offer entered by a Market Maker that is firm and may update the Market Maker's previous quote, if any. The Rules of the Exchange provide for the use of different types of quotes, including Standard quotes and eQuotes, as more fully described in Exchange Rule 517. A Market Maker may, at times, choose to have multiple types of quotes active in an individual option. *See* Exchange Rule 100.

[5] The term ''Simple Order Book'' means the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 518(a)(17).

[6] *See* Fee Schedule, Section 6)a).

[7] In sum, a ''Complex Order'' is ''any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the 'legs' or 'components' of the complex order), for the same account . . . . '' *See* Exchange Rule 518(a)(5).

[8] The ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(19).

[9] The term ''complex strategy'' means a particular combination of components and their ratios to one another. New complex strategies can be created as the result of the receipt of a complex order or by the Exchange for a complex strategy that is not

based on displayable orders in the complex strategy. The cToM data feed also provides subscribers with the following information: (i) the identification of the complex strategies currently trading on the Exchange; (ii) complex strategy last sale information; and (iii) the status of securities underlying the complex strategy (*e.g.,* halted, open, or resumed). ToM subscribers are not required to subscribe to cToM, and cToM subscribers are not required to subscribe to ToM.

The Exchange notes that there is no requirement that any Member [10] or market participant subscribe to either the ToM or cToM data feeds. Instead, a Member may choose to maintain subscriptions to ToM or cToM based on their trading strategies and individual business decisions. Moreover, persons (including broker-dealers) who subscribe to any exchange proprietary data feed must also have equivalent access to consolidated Options Information [11] from the Options Price Reporting Authority (''OPRA'') for the same classes or series of options that are included in the proprietary data feed (including for exclusively listed products), and proprietary data feeds cannot be used to meet that particular requirement. The proposed fees described below would not apply differently based upon the size or type of firm, but rather based upon the type of subscription a firm has to ToM or cToM and their use thereof, which are based upon factors deemed relevant by each firm. The proposed pricing for ToM and cToM is set forth below.[12]

ToM

The Exchange currently charges a monthly fee of $1,250 to Internal Distributors [13] and $1,750 to External Distributors. The Exchange proposes to charge a monthly fee of $2,000 to Internal Distributors and $3,000 to External Distributors. The proposed fee increases are intended to cover the Exchange's increasing costs with compiling and producing the ToM data feed described in the Exchange's Cost Analysis detailed below. The Exchange does not currently charge, nor does it now propose to charge any additional fees based on a Distributor's use of the ToM and cToM data feeds (*e.g.,* displayed versus non-displayed use), redistribution fees, or individual per user fees.

cToM

The Exchange previously adopted rules governing the trading of Complex Orders in 2016.[14] At that time, the Exchange also adopted the cToM data feed and expressly waived fees over six years to incentivize market participants to subscribe and make the Exchange's cToM data more widely available.[15] In the eight years since the Exchange adopted Complex Order functionality, the Exchange has grown its monthly complex market share from 0% to 11.47% of the total electronic complex non-index volume executed on exchanges offering electronic complex functionality based on the month of January 2024.[16] During that same period, the Exchange experienced a steady increase in the number of cToM subscribers. Until the Exchange initially filed to adopt cToM fees in July of 2021,[17] the Exchange did not charge fees for subscriptions to the cToM data feed. The objective of this approach was to eliminate any fee-based barriers for Members when the Exchange first launched Complex Order functionality, which the Exchange believed was necessary to attract order flow as a relatively new exchange at that time. During that time, the Exchange absorbed all costs associated with compiling and disseminating the cToM data feed. The Exchange now proposes to establish fees for the cToM data feed to recoup its ongoing costs going forward, as described below.

The Exchange proposes to charge a monthly fee of $2,000 to Internal Distributors and $3,000 to External Distributors of the cToM data feed. The proposed fees are identical to those proposed herein for the ToM data feed. The Exchange proposes to assess Internal Distributors fees that are less than the fees assessed for External Distributors because External Distributors may monetize their receipt of the ToM and cToM data feeds by charging their customers fees for receipt of the Exchange's data. Internal Distributors do not have the same ability. Like the ToM data feed, the Exchange does not propose to adopt separate redistribution fees for the cToM data feed. However, the recipient of cToM data would be required to become a Distributor and would be subject to the applicable Distribution fees. Also like the ToM data feed, the Exchange does not propose to charge individual per user fees or any additional fees based on a subscriber's use of the cToM data feed (*e.g.,* displayed versus non-displayed use).

The Exchange proposes to assess cToM fees to Internal and External Distributors in the same manner as it currently does for the ToM data feed. Each Distributor would be charged for each month it is credentialed to receive cToM in the Exchange's production environment. Also, fees for cToM will be reduced for new mid-month Distributors for the first month they subscribe. New mid-month cToM Distributors would be assessed a pro-rata percentage of the applicable Distribution fee based on the percentage of the number of trading days remaining in the affected calendar month as of the

currently in the System. The Exchange may limit the number of new complex strategies that may be in the System at a particular time and will communicate this limitation to Members via Regulatory Circular. *See* Exchange Rule 518(a)(6).

[10] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] The term ''consolidated Options Information'' means ''consolidated Last Sale Reports combined with either consolidated Quotation Information or the BBO furnished by OPRA . . . '' Access to consolidated Options Information is deemed ''equivalent'' if both kinds of information are equally accessible on the same terminal or work station. *See* Limited Liability Company Agreement of Options Price Reporting Authority, LLC (''OPRA Plan''), Section 5.2(c)(iii). The Exchange notes that this requirement under the OPRA Plan is also reiterated under the Cboe Global Markets Global Data Agreement and Cboe Global Markets North American Data Policies, which subscribers to any exchange proprietary product must sign and are subject to, respectively. Additionally, the Exchange's Data Order Form (used for requesting the Exchange's market data products) requires confirmation that the requesting market participant receives data from OPRA.

[12] The Exchange first filed the proposed fee change on December 28, 2022. *See* Securities Exchange Act Release No. 96626 (January 10, 2023), 88 FR 2699 (January 17, 2023) (SR–MIAX–2022–49). After several withdrawals and re-filings, the Commission Staff suspended the proposed fees on August 3, 2023. *See* Securities Exchange Act Release No. 98050 (August 3, 2023), 88 FR 53941 (August 9, 2023) (SR–MIAX–2023–23). On January 17, 2024, the Exchange withdrew the suspended proposed fee change. *See* Securities Exchange Act Release No. 99408 (January 22, 2024), 89 FR 5271 (January 26, 2024).

[13] A ''Distributor'' of MIAX data is any entity that receives a feed or file of data either directly from MIAX or indirectly through another entity and then distributes it either internally (within that entity) or externally (outside that entity). All Distributors are required to execute a MIAX Distributor Agreement. *See* Fee Schedule, Section 6)a).

[14] *See* Securities Exchange Act Release No. 79072 (October 7, 2016), 81 FR 71131 (October 14, 2016) (SR–MIAX–2016–26) (Order Approving a Proposed Rule Change to Adopt New Rules to Govern the Trading of Complex Orders).

[15] *See* Securities Exchange Act Release No. 79146 (October 24, 2016), 81 FR 75171 (October 28, 2016) (SR–MIAX–2016–36) (providing a complete description of the cToM data feed).

[16] The Exchange notes that it receives complex market data for all U.S. options exchanges that offer complex functionality from direct feeds from OPRA.

[17] *See* Securities Exchange Act Release Nos. 92359 (July 9, 2021), 86 FR 37393 (July 15, 2021) (SR–MIAX–2021–28); 98050 (August 3, 2023), 88 FR 53941 (August 9, 2023) (SR–MIAX–2023–23) (Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Increase Fees for the ToM Market Data Product and Establish Fees for the cToM Market Data Product).

date on which they have been first credentialed to receive cToM in the production environment, divided by the total number of trading days in the affected calendar month.

Minor, Non-Substantive Changes

The Exchange also proposes to amend the paragraph below the table of fees for ToM and cToM in Section 6)a) of the Fee Schedule to make a minor, non-substantive correction by deleting the phrase ''(as applicable)'' in the first sentence following the table of fees for ToM and cToM. The purpose of this proposed change is to remove unnecessary text from the Fee Schedule. This proposed change does not alter the operation of either fee.

Implementation

The proposed fee changes are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [18] of the Act in general, and furthers the objectives of Section 6(b)(4) [19] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) [20] of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In 2019, Commission staff published guidance suggesting the types of information that self-regulatory organizations (''SROs'') may use to demonstrate that their fee filings comply with the standards of the Exchange Act (the ''Staff Guidance'').[21] While the Exchange understands that the Staff Guidance does not create new legal obligations on SROs, the Staff Guidance is consistent with the Exchange's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. The Staff Guidance provides that in assessing the reasonableness of a fee, the Staff would consider whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, the Staff Guidance further provides that the Staff would consider whether the evidence provided by an SRO in a Fee Filing proposal demonstrates (i) that there are reasonable substitutes for the product or service that is the subject of a proposed fee; (ii) that ''platform'' competition constrains the fee; and/or (iii) that the revenue and cost analysis provided by the SRO otherwise demonstrates that the proposed fee would not result in the SRO taking supra-competitive profits.[22] The Exchange provides sufficient evidence below to support the findings that the proposed fees are reasonable because the projected revenue and cost analysis contained herein demonstrates that the proposed fees would not result in the Exchange taking supra-competitive profits.

As noted above, the Exchange also adopted the cToM data feed and expressly waived fees over six years to incentivize market participants to subscribe and make the Exchange's cToM data more widely available.[23] In the eight years since the Exchange adopted Complex Order functionality, the Exchange has grown its monthly complex market share from 0% to 11.47% of the total electronic complex non-index volume executed on U.S. options exchanges offering complex functionality for the month of January 2024. One of the primary objectives of the Exchange is to provide competition and to reduce fixed costs imposed upon the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

Accordingly, in proposing to charge fees for market data, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Members—both generally and in relation to other Members—to ensure the fees will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange does not believe it needs to otherwise address questions about market competition in the context of this filing because the proposed fees are consistent with the Act based on its Cost Analysis. The Exchange also believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[24] and Rule 19b–4 thereunder,[25] with respect to the types of information SROs should provide when filing fee changes, and Section 6(b) of the Act,[26] which requires, among other things, that exchange fees be reasonable and equitably allocated,[27] not designed to permit unfair discrimination,[28] and that they do not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.[29] This proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.

In 2019, the Exchange completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis'').[30] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk functionality, the

[18] 15 U.S.C. 78f.

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78f(b)(5).

[21] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[22] *Id.*

[23] *See supra* note 15.

[24] 15 U.S.C. 78s(b)(1).

[25] 17 CFR 240.19b–4.

[26] 15 U.S.C. 78f(b).

[27] 15 U.S.C. 78f(b)(4).

[28] 15 U.S.C. 78f(b)(5).

[29] 15 U.S.C. 78f(b)(8).

[30] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers'').

As an initial step, the Exchange determined the total cost for the Exchange and its affiliated markets [31] for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[32] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all cost drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below. For instance, fixed costs that are not driven by client activity (*e.g.,* message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (for example, 59% of the data center total expense amount is allocated to 10Gb ULL connectivity), with smaller allocations to ToM and cToM (1.3% combined), and the remainder to the provision of other connectivity, ports, transaction execution, membership services and other market data services (39.7%). This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below. Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other cost-justified potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive Cost Analysis, which was again recently further refined, the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of ToM and cToM data feeds, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of ToM and

[31] The affiliated markets include Miami International Securities Exchange, LLC (''MIAX''); separately, the options and equities markets of MIAX PEARL, LLC (''MIAX Pearl''); and MIAX Emerald, LLC (''MIAX Emerald'').

[32] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

cToM data feeds, and thus bears a relationship that is, ''in nature and closeness,'' directly related to ToM and cToM data feeds. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide ToM and cToM data feeds is $74,789 (the Exchange divided the annual cost for each of ToM and cToM by 12 months, then added both numbers together), as further detailed below.

Costs Related to Offering ToM and cToM Data Feeds

The following chart details the individual line-item (annual) costs considered by the Exchange to be related to offering the ToM and cToM data feeds to its Members and other customers, as well as the percentage of the Exchange's overall costs that such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 2.6% of its overall Human Resources cost to offering ToM and cToM data feeds).

Cost drivers	Allocated annual cost [a]	Allocated monthly cost [b]	% of all
Human Resources	$588,806	$49,067	2.6
Connectivity (external fees, cabling, switches, etc.)	1,205	101	1.3
Internet Services and External Market Data	0.00	0.00	0.0
Data Center	19,292	1,608	1.3
Hardware and Software Maintenance & Licenses	26,386	2,199	1.3
Depreciation	35,967	2,997	0.8
Allocated Shared Expenses	225,807	18,817	2.5
Total	897,463	74,789	2.2

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering ToM and cToM. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated market, MIAX Emerald, in its similar proposed fee change for ToM and cToM. This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace. The Exchange provides additional explanation below (including the reason for the deviation) for the significant differences, if any.

The Exchange also notes that expenses included in its 2024 fiscal year budget and this proposal are generally higher than its 2023 fiscal year budget and Cost Analysis included in prior filings. This is due to a number of factors, such as, critical vendors and suppliers increasing costs they charge the Exchange, significant exchange staff headcount increases, increased data center costs from the Exchange's data center providers in multiple locations and facilities, higher technology and communications costs, planned hardware refreshes, and system capacity upgrades that increase depreciation expense. Specifically, with regard to employee compensation, the 2024 fiscal year budget includes additional expenses related to increased headcount and new hires that are needed to support the Exchange as it continues to grow (the Exchange and its affiliated companies are projected to hire over 60 additional staff in 2024). Hardware and software expenses have also increased primarily due to price increases from critical vendors and equipment suppliers. Further, the Exchange budgeted for additional hardware and software needs to support the Exchange's continued growth and expansion. Depreciation and amortization have likewise increased due to recent and planned refreshes in Exchange hardware and software. This new equipment and software then becomes depreciable, as described below. Data center costs have also increased due the following: the Exchange expanding its footprint within its data center; and the data center vendor increasing the costs it charges the Exchange. Lastly, allocated shared expenses have increased due to the overall budgeted increase in costs from 2023 to 2024 necessary to operate and support the Exchange as described below.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining ToM and cToM data feeds and performance thereof (primarily the Exchange's network infrastructure team, which spends a portion of their time performing functions necessary to provide market data). As described more

fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to market data. From that portion allocated to the Exchange that applied to market data, the Exchange then allocated a weighted average of 2.6% of each employee's time from the above group to ToM and cToM data feeds (which excludes an allocation for the recently hired Head of Data Services for the Exchange and its affiliates).

The Exchange also allocated Human Resources costs to provide ToM and cToM to a limited subset of personnel with ancillary functions related to establishing and maintaining such market data feeds (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing market data feeds) and then applied a smaller allocation to such employees' time to ToM and cToM (less than 1.7%, which includes an allocation for the Head of Data Services). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to providing ToM and cToM, whether it is a sales person selling a market data feed, finance personnel billing for market data feeds or providing budget analysis, or information security ensuring that such market data feeds are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing market data feeds, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing ToM and cToM data feeds: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated 2.6% of each of their employee's time assigned to the Exchange for ToM and cToM, as stated above. Employees from these departments perform numerous functions to support ToM and cToM data feeds, such as the configuration and maintenance of the hardware necessary to support the ToM and cToM data feeds. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting ToM and cToM data feeds and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support ToM and cToM, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the ToM and cToM related Human Resources costs to the extent that they are involved in overseeing tasks related to providing market data. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, Etc.) [33]

The Connectivity cost driver includes cabling and switches required to generate and disseminate the ToM and cToM data feeds and operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete Member subscriptions to ToM and cToM and the servers used at the Exchange's primary and back-up data centers specifically for the ToM and cToM data feeds. Further, as certain servers are only partially utilized to generate and disseminate the ToM and cToM data feeds, only the percentage of such servers devoted to generating and disseminating the ToM and cToM data feeds was included (*i.e.,* the capacity of such servers allocated to the ToM and cToM data feeds).[34]

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. External market data includes fees paid to third parties, including other exchanges, to receive market data. The Exchange did not allocate any costs associated with internet services or external market data to the ToM and cToM data feeds.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide ToM and cToM in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange does not own the primary data center or the secondary data center, but instead leases space in data centers operated by third parties. As the Data Center costs are primarily for space, power, and cooling of servers, the Exchange allocated 1.3% to the applicable Data Center costs for the ToM and cToM data feeds. The Exchange believes it is reasonable to apply the same proportionate percentage of Data Center costs to that of the Connectivity cost driver.

Hardware and Software Maintenance and Licenses

Hardware and Software Maintenance and Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer the ToM and cToM data feeds.[35] Because the hardware and software license fees are correlated to the servers

[33] This cost driver was titled ''Network Infrastructure'' in prior proposals. The Exchange has updated this section to now be in line with its similar cost analysis and cost driver descriptions for other non-transaction fee filings. *See, e.g.,* Securities Exchange Act Release No. 99476 (February 5, 2024), 89 FR 9194 (February 9, 2024) (SR–MIAX–2024–06).

[34] The Exchange understands that the Investors Exchange, Inc. (''IEX'') and MEMX LLC (''MEMX'') both allocated a percentage of their servers to the production and dissemination of market data to support proposed market data fees. *See* Securities Exchange Act Release Nos. 94630 (April 7, 2022), 87 FR 21945, at page 21949 (April 13, 2022) (SR–IEX–2022–02) *and* 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04). The Exchange does not have insight into either MEMX's or IEX's technology infrastructure or what their determinations were based on. However, the Exchange reviewed its own technology infrastructure and believes based on its design, it is more appropriate for the Exchange to allocate a portion of its Connectivity cost driver to market data based on a percentage of overall cost, not on a per server basis.

[35] This expense may be more than the Exchange's affiliated markets, specifically MIAX Emerald. This is because each market may maintain and utilize a different amount of hardware and software based on its market model and infrastructure needs. The Exchange allocated a percentage of the overall cost based on actual amounts of hardware and software utilized by that market, which resulted in different cost allocations and dollar amounts.

used by the Exchange, the Exchange again applied an allocation of 1.3% of its costs for Hardware and Software Maintenance and Licenses to the ToM and cToM data feeds. The Exchange notes that this allocation is more than MIAX Emerald as MIAX allocated 1.3% of its Hardware and Software Maintenance and License expense to ToM and cToM, while MIAX Emerald allocated 1.1% of its Hardware and Software Maintenance and License expense to ToM and cToM. MIAX's allocation results in a slightly higher dollar amount of $8,000 per year (or approximately $667 per month, when dividing the annual cost difference by 12 months and rounding to the nearest dollar) compared to the annual cost of MIAX Emerald for its Hardware and Software Maintenance and License cost driver. This is because MIAX is in the process of replacing and upgrading various hardware and software used to operate its options trading platform in order to maintain premium network performance, including dissemination of ToM and cToM. At the time of this filing, MIAX is undergoing a major hardware refresh, replacing older hardware with new hardware. This hardware includes servers, network switches, cables, optics, protocol data units, and cabinets, to maintain a state-of-the-art technology platform. Because of the timing of the hardware refresh with the timing of this filing, MIAX has a slightly higher expense than MIAX Emerald.

Depreciation

All physical assets, software, and hardware used to provide ToM and cToM, which also includes assets used for testing and monitoring of Exchange infrastructure to provide market data, were valued at cost, and depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes. The vast majority of the software the Exchange uses for its operations to generate and disseminate the ToM and cToM data feeds has been developed in-house over an extended period. This software development also requires quality assurance and thorough testing to ensure the software works as intended. The Exchange also included in the Depreciation cost driver certain budgeted improvements that the Exchange intends to capitalize and depreciate with respect to ToM and cToM in the near-term. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost was therefore narrowly tailored to depreciation related to ToM and cToM. As noted above, the Exchange allocated 0.8% of its allocated depreciation costs to providing ToM and cToM.

The Exchange notes that this allocation differs from its affiliated market, MIAX Emerald, due to a number of factors, such as the age of physical assets and software (*e.g.,* older physical assets and software were previously depreciated and removed from the allocation), or certain system enhancements that required new physical assets and software, thus providing a higher contribution to the depreciated cost. For example, the Exchange notes that the percentages it and its affiliate, MIAX Emerald, allocated to the depreciation of software and hardware used to generate and disseminate their respective ToM and cToM data feeds are similar (0.8% for MIAX and 0.5% for MIAX Emerald). However, MIAX's dollar amount is greater than that of MIAX Emerald by approximately $17,000 per year (albeit a relatively small amount of approximately $1,415 per month, when rounding to the nearest dollar). This is due to two primary factors. First, the Exchange has undergone a technology refresh since the time MIAX Emerald launched in February 2019, leading to it having more hardware and software that is subject to depreciation. Second, the Exchange maintains 24 matching engines while MIAX Emerald maintains only 12 matching engines. This also results in more of the Exchange's hardware and software being subject to depreciation than MIAX Emerald's hardware and software due to the greater amount of equipment and software necessary to support the greater number of matching engines on the Exchange.

Allocated Shared Expenses

Finally, as with other exchange products and services, a portion of general shared expenses was allocated to the provision of ToM and cToM data feeds. These general shared costs are integral to exchange operations, including its ability to provide ToM and cToM. Costs included in general shared expenses include office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications. Similarly, the cost of paying directors to serve on the Exchange's Board of Directors is also included in the Exchange's general shared expense cost driver.[36] These general shared expenses are incurred by the Exchange's parent company, MIH, as a direct result of operating the Exchange and its affiliated markets.

The Exchange employed a process to determine a reasonable percentage to allocate general shared expenses to ToM and cToM pursuant to its multi-layered allocation process. First, general expenses were allocated among the Exchange and affiliated markets as described above. Then, the general shared expense assigned to the Exchange was allocated across core services of the Exchange, including market data. Then, these costs were further allocated to sub-categories within the final categories, *i.e.,* ToM and cToM as sub-categories of market data. In determining the percentage of general shared expenses allocated to market data that ultimately apply to ToM and cToM, the Exchange looked at the percentage allocations of each of the cost drivers and determined a reasonable allocation percentage. The Exchange also held meetings with senior management, department heads, and the Finance Team to determine the proper amount of the shared general expense to allocate to ToM and cToM. The Exchange, therefore, believes it is reasonable to assign an allocation, in the range of allocations for other cost drivers, while continuing to ensure that this expense is only allocated once. Again, the general shared expenses are incurred by the Exchange's parent company as a result of operating the Exchange and its affiliated markets and it is therefore reasonable to allocate a percentage of those expenses to the Exchange and ultimately to specific product offerings such as ToM and cToM.

Again, a portion of all shared expenses were allocated to the Exchange (and its affiliated markets) which, in turn, allocated a portion of that overall allocation to all market data products offered by the Exchange. The Exchange then allocated 2.5% of the portion allocated to market data to ToM and cToM. The Exchange believes this allocation percentage is reasonable because, while the overall dollar amount may be higher than other cost drivers, the 2.5% is based on and in line with the percentage allocations of each

[36] The Exchange notes that MEMX allocated a precise amount of 10% of the overall cost for directors in a similar non-transaction fee filing. *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04). The Exchange does not calculate is expenses at that granular a level. Instead, director costs are included as part of the overall general allocation.

of the Exchange's other cost drivers. The percentage allocated to ToM and cToM also reflects its importance to the Exchange's strategy and necessity towards the nature of the Exchange's overall operations, which is to provide a resilient, highly deterministic trading system that relies on faster market data feeds than the Exchange's competitors to maintain premium performance. This allocation reflects the Exchange's focus on providing and maintaining high performance market data services, of which ToM and cToM are main contributors.

The Exchange notes that this allocation differs from its affiliated market, MIAX Emerald, due to a number of factors, such as the increase in overall headcount, thus providing a higher contribution to the depreciated cost. The Exchange notes that the percentages it and its affiliate, MIAX Emerald, allocated to this cost driver are similar (2.5% for MIAX and 2.1% for MIAX Emerald). However, MIAX's dollar amount is greater than that of MIAX Emerald by $38,096 per year (albeit a relatively small amount of approximately $3,174 per month, when rounding to the nearest dollar). This is due primarily to significant exchange staff headcount increases.[37] As mentioned above, the 2024 fiscal year budget includes additional expenses related to increased headcount and new hires that are needed to support the Exchange as it continues to grow (with a projected 60 additional staff in 2024). Lastly, allocated shared expenses have increased due to the overall budgeted increase in costs from 2023 to 2024 necessary to operate and support the Exchange and its affiliated markets.

* * * * *

Approximate Cost for ToM and cToM per Month

After determining the approximate allocated monthly cost related to ToM and cToM combined, the total monthly cost for ToM and cToM of $74,789 was divided by the number of total subscribers to ToM and cToM that the Exchange maintained in August 2023 (33 Internal Distributors + 7 External Distributors = 40 total Distributors),[38] to arrive at a cost of approximately $1,870 per month per subscription (rounded to the nearest dollar). Due to the nature of this particular cost, this allocation methodology results in an allocation among the Exchange and its affiliated markets based on set quantifiable criteria, *i.e.,* actual number of ToM and cToM subscribers.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service (including market data) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filings the Exchange recently submitted proposing fees for certain connectivity and ports offered by the Exchange. For instance, in calculating the Human Resources expenses to be allocated to market data based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a commensurate percentage of the cost of such personnel (6.1%) given their focus on functions necessary to provide market data. The salaries of those same personnel were allocated only 2.6% to ToM and cToM and the remaining 97.4% was allocated to other market data products offered by the Exchange (MOR, AIS, etc.), connectivity services, port services, transaction services, and membership services. The Exchange did not allocate any other Human Resources expense for providing market data to any other employee group, outside of a smaller allocation of 1.7% for ToM and cToM of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel.

In total, the Exchange allocated 2.6% of its personnel costs (Human Resources) to providing ToM and cToM. In turn, the Exchange allocated the remaining 97.4% of its Human Resources expense to membership services, transaction services, connectivity services, port services and other market data products. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including market data, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide ToM and cToM data feeds to its Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing ToM and cToM, but instead allocated approximately 0.8% of the Exchange's overall depreciation and amortization expense to ToM and cToM combined. The Exchange allocated the remaining depreciation and amortization expense (99.2%) toward the cost of providing transaction services, membership services, connectivity services, port services, and other market data products.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from ToM and cToM, the Exchange will have to be successful in retaining existing clients that wish to maintain subscriptions to those market data feeds or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of market data services it will receive additional revenue to offset future cost increases. However, if use of market data services is static or decreases, the Exchange might not realize the revenue that it anticipates or

[37] The Exchange notes that this reference to increased headcount is used here to explain why MIAX's dollar amount of its allocated shared expense is greater than that of MIAX Emerald. A similar reference is not included in the above discussion of the Human Resources cost driver because the description of that cost driver does not include a similar comparison.

[38] The Exchange used August 2023 subscription data because that was the last full month the fees proposed herein for ToM and cToM were charged, before the Exchange's prior filing to adopt the same fees was suspended by the Commission. *See supra* note 12. While there has been no material overall change to the number of subscriptions since August 2023, the Exchange notes that the number of subscriptions may fluctuate and demand may change when fees are removed and reinstated. Accordingly, the Exchange believes that, in order to obtain an accurate measure of actual demand for fee-liable subscriptions, the Exchange looked to the last month that the fees were in place prior to suspension, which was August 2023.

needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [39]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with creating, generating, and disseminating the ToM and cToM data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for market data subscribers. Subscribers, particularly those of ToM and cToM, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide ToM and cToM will equal $897,463. Based on current ToM and cToM subscribers, the Exchange would generate annual revenue of approximately $1,040,880 for ToM and cToM combined.[40] The Exchange believes this represents a modest profit of 13.8% when compared to the cost of providing ToM and cToM data feeds.

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing ToM and cToM data feeds versus the total projected revenue of the Exchange associated with ToM and cToM.

The Exchange also notes that the resultant profit margin differs slightly from the profit margins set forth in a similar fee filing by its affiliated market, MIAX Emerald. This is not atypical among exchanges and is due to a number of factors that differ between these two markets, including: different market models, market structures, and product offerings (price-time, pro-rata, simple, and complex); different pricing models; different number of market participants and connectivity subscribers; different maintenance and operations costs, as described in the cost allocation methodology above; different technical architecture (*e.g.,* the number of matching engines per exchange, *i.e.,* MIAX maintains 24 matching engines while MIAX Emerald maintains only 12 matching engines); and different maturity phase of MIAX and its affiliated markets (*i.e.,* start-up versus growth versus more mature). All of these factors contribute to a unique and differing level of profit margin per exchange.

Further, MIAX and MIAX Emerald propose to charge the same rates for their respective ToM and cToM data feeds, which are comparable to, or lower than, similar fees for similar products charged by competing exchanges. For example, for Internal Distributors of ToM and cToM, the Exchange proposes a lower fee than the fee charged by ISE for ISE's Top Quote Feed ($2,000 for the Exchange vs. $3,000 for ISE).[41] NYSE Arca charges even higher fees for the NYSE Arca Options Top Feed than the Exchange's proposed fees ($2,000 for the Exchange vs. $3,000 per month plus an additional $2,000 for redistribution on NYSE Arca).[42] Accordingly, the Exchange believes that comparable and competitive pricing are key factors in determining whether a proposed fee meets the requirements of the Act, regardless of whether that same fee across the Exchange's affiliated markets leads to slightly different profit margins due to factors outside of the Exchange's control (*i.e.,* more subscribers to ToM and/or cToM on MIAX or MIAX Emerald and vice versa).

The Exchange also reiterates that prior to July of 2021, the month in which it first proposed to adopt fees for cToM, the Exchange did not charge any fees for cToM and its allocation of costs to cToM was part of a holistic allocation that also allocated costs to other core services without double-counting any expenses. The Exchange is owned by a holding company that is the parent company of four exchange markets and, therefore, the Exchange and its affiliated markets must allocate shared costs across all of those markets accordingly, pursuant to the above-described allocation methodology. In contrast, IEX and MEMX, which are currently each operating only one exchange, in their recent non-transaction fee filings allocate the entire amount of that same cost to a single exchange. This can result in lower profit margins for the non-transaction fees proposed by IEX and MEMX because the single allocated

[39] For purposes of calculating projected annualized 2024 revenue for ToM and cToM, the Exchange used monthly revenues for August 2023, the last month the Exchange billed at the proposed rates before the Commission suspended the earlier filing. *Id.*

[40] The Exchange notes that the total revenue number of $1,040,880 does not equal the full monthly fee multiplied by the total number of Distributors, due to a new Distributor first purchasing a ToM and cToM data feed mid-month and having their first month's fee(s) pro-rated for External Distribution, pursuant to Section 6)a) of the Exchange Fee Schedule.

[41] *See* ISE Options 7 Pricing Schedule, Section 10, H., *available at https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207* (assessing Professional internal and external distributors $3,000 per month, plus $20 per month per controlled device for ISE's Top Quote Feed).

[42] Fees for the NYSE Arca Options Top Feed, which is the comparable product to ToM, are $3,000 per month for access (internal use) and an additional $2,000 per month for redistribution (external distribution), compared to the Exchange's proposed fees of $2,000 and $3,000 for Internal and External Distributors, respectively. In addition, for its NYSE Arca Options Top Feed, NYSE Arca charges for three different categories of non-display usage, and user fees, both of which the Exchange does not propose to charge, causing the overall cost of NYSE Arca Options Top Feed to far exceed the Exchange's proposed rates. *See* NYSE Arca Options Proprietary Market Data Fees, *available at: https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Options_Proprietary_Data_Fee_Schedule.pdf.*

cost does not experience the efficiencies and synergies that result from sharing costs across multiple platforms.[43] The Exchange and its affiliated markets often share a single cost, which results in cost efficiencies that can cause a broader gap between the allocated cost amount and projected revenue, even though the fee levels being proposed are lower or competitive with competing markets (as described above). To the extent that the application of a cost-based standard results in Commission Staff making determinations as to the appropriateness of certain profit margins, the Commission Staff should consider whether the proposed fee level is comparable to, or competitive with, the same fee charged by competing exchanges and how different cost allocation methodologies (such as across multiple markets) may result in different profit margins for comparable fee levels. If Commission Staff is making determinations as to appropriate profit margins, the Exchange believes that the Commission should be clear to all market participants as to what they have determined is an appropriate profit margin and should apply such determinations consistently and, in the case of certain legacy exchanges, retroactively, if such standards are to avoid having a discriminatory effect. Further, the proposal reflects the Exchange's efforts to control its costs, which the Exchange does on an ongoing basis as a matter of good business practice. A potential profit margin should not be judged alone based on its size, but is also indicative of costs management and whether the ultimate fee reflects the value of the services provided. For example, a profit margin on one exchange should not be deemed excessive where that exchange has been successful in controlling its costs, but not excessive where on another exchange where that exchange is charging comparable fees but has a lower profit margin due to higher costs. Doing so could have the perverse effect of not incentivizing cost control where higher costs alone are used to justify fees increases.

Accordingly, while the Exchange is supportive of transparency around costs and potential margins (applied across all exchanges), as well as periodic review of revenues and applicable costs (as discussed below), the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning—or seeking to earn—supra-competitive profits, the standard set forth in the Staff Guidance. The Exchange believes the Cost Analysis and related projections in this filing demonstrate this fact.

Reasonableness

Overall. With regard to reasonableness, the Exchange understands that the Commission has traditionally taken a market-based approach to examine whether the exchange making the fee proposal was subject to significant competitive forces in setting the terms of the proposal. The Exchange understands that in general the analysis considers whether the exchange has demonstrated in its filing that (i) there are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the exchange taking supra-competitive profits. If the exchange demonstrates that the fee is subject to significant competitive forces, the Exchange understands that in general the analysis will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. The Exchange further understands that if the filing fails to demonstrate that the fee is constrained by competitive forces, the exchange must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

The Exchange has not determined its proposed overall market data fees based on assumptions about market competition, instead relying upon a cost-plus model to determine a reasonable fee structure that is informed by the Exchange's understanding of different uses of the products by different types of participants. In this context, the Exchange believes the proposed fees overall are fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for the Exchange's aggregate costs of offering the ToM and cToM data feeds. The Exchange believes the proposed fees are reasonable because they are designed to generate annual revenue to recoup some or all of Exchange's annual costs of providing ToM and cToM data with a reasonable mark-up. As discussed in the Purpose section, the Exchange estimates this fee filing will result in annual revenue of approximately $1,040,880, representing a potential mark-up of just 13.8% over the cost of providing ToM and cToM data. Accordingly, the Exchange believes that this fee methodology is reasonable because it allows the Exchange to recoup all of its expenses for providing the ToM and cToM data products (with any additional revenue representing no more than what the Exchange believes to be a reasonable rate of return). The Exchange also believes that the proposed fees are reasonable because they are generally less than the fees charged by competing options exchanges for comparable market data products, notwithstanding that the competing exchanges may have different system architectures that may result in different cost structures for the provision of market data.

The Exchange believes the proposed fees for the ToM and cToM data feeds are reasonable when compared to fees for comparable products, compared to which the Exchange's proposed fees are generally lower, as well as other comparable data feeds priced significantly higher than the Exchange's proposed fees for the ToM and cToM data feeds.

Internal Distribution Fees. The Exchange believes that it is reasonable to charge fees to access the ToM and cToM data feeds for Internal Distribution because of the value of such data to subscribers in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fee for cToM is reasonable as it is similar to the amount charged by at least one other exchange of comparable size for comparable data products, and lower than the fees charged by other exchanges for comparable data products.[44]

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the ToM and cToM data feeds because vendors receive value from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable

[43] The Exchange acknowledges that IEX included in its proposal to adopt market data fees after offering market data for free an analysis of what its projected revenue would be if all of its existing customers continued to subscribe versus what its projected revenue would be if a limited number of customers subscribed due to the new fees. *See* Securities Exchange Act Release No. 94630 (April 7, 2022), 87 FR 21945 (April 13, 2022) (SR–IEX–2022–02). MEMX did not include a similar analysis in either of its recent non-transaction fee proposals. *See, e.g., supra* note 34. The Exchange does not believe a similar analysis would be useful here because it is amending existing fees, not proposing to charge a new fee where existing subscribers may terminate connections because they are no longer enjoying the service at no cost.

[44] *See supra* notes 41 and 42.

because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fees would be charged only once per month to each vendor account that redistributes any ToM and cToM data feeds, regardless of the number of customers to which that vendor redistributes the data. For all of the foregoing reasons, the Exchange believes that the proposed fees for the ToM and cToM data feeds are reasonable.

Equitable Allocation

Overall. The Exchange believes that its proposed fees are reasonable, fair, and equitable, and not unfairly discriminatory because they are designed to align fees with services provided. The Exchange believes the proposed fees for the ToM and cToM data feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the ToM and cToM data feeds. Any subscriber or vendor that chooses to subscribe to the ToM and cToM data feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more ToM and cToM data feeds is based on objective differences in usage of ToM and cToM data feeds among different Members, which are still ultimately in the control of any particular Member. The Exchange believes the proposed pricing of the ToM and cToM data feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed and the value of that information to market participants.

Internal Distribution Fees. The Exchange believes the proposed monthly fees for Internal Distribution of the ToM and cToM data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the ToM and cToM data feeds for internal distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for External Distribution of the ToM and cToM data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the ToM and cToM data feeds that choose to redistribute the feeds externally, regardless of what business they operate. The Exchange also believes that the proposed monthly fees for External Distribution are equitably allocated when compared to lower proposed fees for Internal Distribution because data recipients that are externally distributing ToM and cToM data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distribution fee is applicable to use by a single data recipient (and its affiliates).

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to assess Internal Distributors fees that are less than the fees assessed for External Distributors for subscriptions to the ToM and cToM data feeds because Internal Distributors have limited, restricted usage rights to the market data, as compared to External Distributors, which have more expansive usage rights. All Members and non-Members that decide to receive any market data feed of the Exchange (or its affiliates, MIAX Pearl and MIAX Emerald), must first execute, among other things, the MIAX Exchange Group Exchange Data Agreement (the ''Exchange Data Agreement'').[45] Pursuant to the Exchange Data Agreement, Internal Distributors are restricted to the ''internal use'' of any market data they receive. This means that Internal Distributors may only distribute the Exchange's market data to the recipient's officers and employees and its affiliates.[46] External Distributors may distribute the Exchange's market data to persons who are not officers, employees or affiliates of the External Distributor,[47] and may charge their own fees for the redistribution of such market data. External Distributors may monetize their receipt of the ToM and cToM data feeds by charging their customers fees for receipt of the Exchange's ToM and cToM data. Internal Distributors do not have the same ability to monetize the Exchange's ToM and cToM data feeds. Accordingly, the Exchange believes it is fair, reasonable and not unfairly discriminatory to assess External Distributors a higher fee for the Exchange's ToM and cToM data feeds as External Distributors have greater usage rights to commercialize such market data and can adjust their own fee structures if necessary.

The Exchange also utilizes more resources to support External Distributors versus Internal Distributors, as External Distributors have reporting and monitoring obligations that Internal Distributors do not have, thus requiring additional time and effort of Exchange staff. For example, External Distributors have monthly reporting requirements under the Exchange's Market Data Policies.[48] Exchange staff must then, in turn, process and review information reported by External Distributors to ensure the External Distributors are redistributing cToM data in compliance with the Exchange's Market Data Agreement and Policies.

The Exchange believes the proposed cToM fees are equitable and not unfairly discriminatory because the fee level results in a reasonable and equitable allocation of fees amongst subscribers for similar services, depending on whether the subscriber is an Internal or External Distributor. Moreover, the decision as to whether or not to purchase market data is entirely optional to all market participants. Potential purchasers are not required to purchase the market data, and the Exchange is not required to make the market data available. Purchasers may request the data at any time or may decline to purchase such data. The allocation of fees among users is fair and reasonable because, if market participants decide not to subscribe to the data feed, firms can discontinue their use of the cToM data.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the ToM and cToM data feeds are equitably allocated.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[49] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed fees place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of the data feed by each market participant based on whether the market participant

[45] *See* Exchange Data Agreement, *available at https://www.miaxglobal.com/markets/us-options/all-options/market-data-vendor-agreements.*

[46] *See id.*

[47] *See id.*

[48] *See* Section 6 of the Exchange's Market Data Policies, *available at https://www.miaxglobal.com/sites/default/files/page-files/MIAX_Exchange_Group_Market_Data_Policies_07202021.pdf.*

[49] 15 U.S.C. 78f(b)(8).

internally or externally distributes the Exchange data, which are still ultimately in the control of any particular Member, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of data consumed by various market participants and their usage thereof.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other exchanges that is not necessary or appropriate. In particular, market participants are not forced to subscribe to either data feed, as described above. Additionally, other exchanges have similar market data fees with comparable rates in place for their participants.[50] The proposed fees are based on actual costs and are designed to enable the Exchange to recoup its applicable costs with the possibility of a reasonable profit on its investment as described in the Purpose and Statutory Basis sections. Competing exchanges are free to adopt comparable fee structures subject to the Commission's rule filing process. Allowing the Exchange, or any new market entrant, to waive fees (as the Exchange did for cToM) for a period of time to allow it to become established encourages market entry and thereby ultimately promotes competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[51] and Rule 19b–4(f)(2)[52] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2024–25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2024–25. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2024–25 and should be submitted on or before May 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Sherry R. Haywood,

Assistant Secretary.

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[50] *See supra* notes 41 and 42.

[51] 15 U.S.C. 78s(b)(3)(A)(ii).

[52] 17 CFR 240.19b–4(f)(2).

[53] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100042; File No. SR–EMERALD–2024–15]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Increase Fees for the ToM Market Data Product and Establish Fees for the cToM Market Data Product

April 26, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 18, 2024, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Emerald Fee Schedule (the ''Fee Schedule'') to (i) amend the fees for the MIAX Emerald Top of Market (''ToM'') data feed; and (ii) establish fees for the MIAX Emerald Complex Top of Market (''cToM'') data feed.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/all-options-exchanges/rule-filings,* at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to: (i) amend the fees for ToM; and (ii) establish fees for cToM. The ToM data feed contains top of book quotations based on options orders [3] and quotes [4] resting on the Exchange's Simple Order Book [5] as well as administrative messages.[6] The cToM data feed includes the same types of information as ToM, but for Complex Orders [7] on the Exchange's Strategy Book.[8] This information includes the Exchange's best bid and offer for a complex strategy,[9] with aggregate size, based on displayable orders in the complex strategy. The cToM data feed also provides subscribers with the following information: (i) the identification of the complex strategies currently trading on the Exchange; (ii) complex strategy last sale information; and (iii) the status of securities underlying the complex strategy (*e.g.,* halted, open, or resumed). ToM subscribers are not required to subscribe to cToM, and cToM subscribers are not required to subscribe to ToM.

The Exchange notes that there is no requirement that any Member [10] or market participant subscribe to either the ToM or cToM data feeds. Instead, a Member may choose to maintain subscriptions to ToM or cToM based on their trading strategies and individual business decisions. Moreover, persons (including broker-dealers) who subscribe to any exchange proprietary data feed must also have equivalent access to consolidated Options Information [11] from the Options Price Reporting Authority (''OPRA'') for the same classes or series of options that are included in the proprietary data feed (including for exclusively listed products), and proprietary data feeds cannot be used to meet that particular requirement. The proposed fees described below would not apply differently based upon the size or type of firm, but rather based upon the type of subscription a firm has to ToM or cToM and their use thereof, which are based upon factors deemed relevant by each firm. The proposed pricing for ToM and cToM is set forth below.[12]

ToM

The Exchange currently charges a monthly fee of $1,250 to Internal Distributors [13] and $1,750 to External Distributors. The Exchange proposes to charge a monthly fee of $2,000 to Internal Distributors and $3,000 to External Distributors. The proposed fee increases are intended to cover the Exchange's increasing costs with compiling and producing the ToM data feed described in the Exchange's Cost Analysis detailed below. The Exchange does not currently charge, nor does it now propose to charge any additional fees based on a Distributor's use of the ToM and cToM data feeds (*e.g.,* displayed versus non-displayed use), redistribution fees, or individual per user fees.

cToM

The Exchange previously adopted rules governing the trading of Complex Orders on the MIAX Emerald System in 2018,[14] ahead of the Exchange's planned launch, which took place on March 1, 2019. Shortly thereafter, the Exchange adopted the cToM data feed product and expressly waived fees for cToM to incentivize market participants to subscribe.[15] In the five years since the Exchange launched operations and adopted Complex Order functionality, the Exchange has grown its monthly complex market share from 0% to 3.53% of the total electronic complex non-index volume executed on exchanges offering electronic complex functionality based on the month of January 2024.[16] During that same period, the Exchange experienced a steady increase in the number of cToM subscribers. Until the Exchange initially filed to adopt cToM fees in July of 2021,[17] the Exchange did not charge fees

[3] The term ''order'' means a firm commitment to buy or sell option contracts. *See* Exchange Rule 100.

[4] The term ''quote'' or ''quotation'' means a bid or offer entered by a Market Maker that is firm and may update the Market Maker's previous quote, if any. The Rules of the Exchange provide for the use of different types of quotes, including Standard quotes and eQuotes, as more fully described in Rule 517. A Market Maker may, at times, choose to have multiple types of quotes active in an individual option. *See* Exchange Rule 100.

[5] The term ''Simple Order Book'' means the Exchange's regular electronic book of orders and quotes. *See* Exchange Rule 518(a)(15).

[6] *See* Fee Schedule, Section 6)a).

[7] In sum, a ''Complex Order'' is ''any order involving the concurrent purchase and/or sale of two or more different options in the same underlying security (the 'legs' or 'components' of the complex order), for the same account . . . .'' *See* Exchange Rule 518(a)(5).

[8] The ''Strategy Book'' is the Exchange's electronic book of complex orders and complex quotes. *See* Exchange Rule 518(a)(17).

[9] The term ''complex strategy'' means a particular combination of components and their ratios to one another. New complex strategies can be created as the result of the receipt of a complex order or by the Exchange for a complex strategy that is not currently in the System. The Exchange may limit the number of new complex strategies that may be in the System at a particular time and will communicate this limitation to Members via Regulatory Circular. *See* Exchange Rule 518(a)(6)

[10] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[11] The term ''consolidated Options Information'' means ''consolidated Last Sale Reports combined with either consolidated Quotation Information or the BBO furnished by OPRA . . .'' Access to consolidated Options Information is deemed ''equivalent'' if both kinds of information are equally accessible on the same terminal or work station. *See* Limited Liability Company Agreement of Options Price Reporting Authority, LLC (''OPRA Plan''), Section 5.2(c)(iii). The Exchange notes that this requirement under the OPRA Plan is also reiterated under the Cboe Global Markets Global Data Agreement and Cboe Global Markets North American Data Policies, which subscribers to any exchange proprietary product must sign and are subject to, respectively. Additionally, the Exchange's Data Order Form (used for requesting the Exchange's market data products) requires confirmation that the requesting market participant receives data from OPRA.

[12] The Exchange first filed the proposed fee change on December 28, 2022. *See* Securities Exchange Act Release No. 96625 (January 10, 2023), 88 FR 2688 (January 17, 2023) (SR–EMERALD–2022–37). After serval withdrawals and re-filings, the Commission Staff suspended the proposed fees on August 3, 2023. *See* Securities Exchange Act Release No. 98051 (August 3, 2023), 88 FR 53937 (August 9, 2023) (SR–EMERALD–2023–13). On January 17, 2024, the Exchange withdrew the suspended proposed fee change. *See* Securities Exchange Act Release No. 99407 (January 22, 2024), 89 FR 5273 (January 26, 2024).

[13] A ''Distributor'' of MIAX Emerald data is any entity that receives a feed or file of data either directly from MIAX Emerald or indirectly through another entity and then distributes it either internally (within that entity) or externally (outside that entity). All Distributors are required to execute a MIAX Emerald Distributor Agreement. *See* Fee Schedule, Section 6)a).

[14] *See* Securities Exchange Act Release Nos. 84891 (December 20, 2018), 83 FR 67421 (December 28, 2018) (In the Matter of the Application of MIAX EMERALD, LLC for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission); *and* 85345 (March 18, 2019), 84 FR 10848 (March 22, 2019) (SR–EMERALD–2019–13) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 518, Complex Orders).

[15] *See* Securities Exchange Act Release No. 85207 (February 27, 2019), 84 FR 7963 (March 5, 2019) (SR–EMERALD–2019–09) (providing a complete description of the cToM data feed).

[16] The Exchange notes that it receives complex market data for all U.S. options exchanges that offer complex functionality from direct feeds from OPRA.

[17] *See* Securities Exchange Act Release Nos. 92358 (July 9, 2021), 86 FR 37361 (July 15, 2021) (SR–EMERALD–2021–21); 98051 (August 3, 2023), 88 FR 53937 (August 9, 2023) (SR–EMERALD–2023–13) (Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Increase Fees

for subscriptions to the cToM data feed. The objective of this approach was to eliminate any fee-based barriers for Members when the Exchange first launched Complex Order functionality, which the Exchange believed was necessary to attract order flow as a relatively new exchange at that time. During that time, the Exchange absorbed all costs associated with compiling and disseminating the cToM data feed. The Exchange now proposes to establish fees for the cToM data feed to recoup its ongoing costs going forward, as described below.

The Exchange proposes to charge a monthly fee of $2,000 to Internal Distributors and $3,000 to External Distributors of the cToM data feed. The proposed fees are identical to those proposed herein for the ToM data feed. The Exchange proposes to assess Internal Distributors fees that are less than the fees assessed for External Distributors because External Distributors may monetize their receipt of the ToM and cToM data feeds by charging their customers fees for receipt of the Exchange's data. Internal Distributors do not have the same ability. Like the ToM data feed, the Exchange does not propose to adopt separate redistribution fees for the cToM data feed. However, the recipient of cToM data would be required to become a Distributor and would be subject to the applicable Distribution fees. Also like the ToM data feed, the Exchange does not propose to charge individual per user fees or any additional fees based on a subscriber's use of the cToM data feed (*e.g.,* displayed versus non-displayed use).

The Exchange proposes to assess cToM fees to Internal and External Distributors in the same manner as it currently does for the ToM data feed. Each Distributor would be charged for each month it is credentialed to receive cToM in the Exchange's production environment. Also, fees for cToM will be reduced for new mid-month Distributors for the first month they subscribe. New mid-month cToM Distributors would be assessed a pro-rata percentage of the applicable Distribution fee based on the percentage of the number of trading days remaining in the affected calendar month as of the date on which they have been first credentialed to receive cToM in the production environment, divided by the total number of trading days in the affected calendar month.

for the ToM Market Data Product and Establish Fees for the cToM Market Data Product).

Minor, Non-Substantive Changes

The Exchange also proposes to amend the paragraph below the table of fees for ToM and cToM in Section 6)a) of the Fee Schedule to make a minor, non-substantive correction by deleting the phrase ''(as applicable)'' in the first sentence following the table of fees for ToM and cToM. The purpose of this proposed change is to remove unnecessary text from the Fee Schedule. This proposed change does not alter the operation of either fee.

Implementation

The proposed fee changes are immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [18] of the Act in general, and furthers the objectives of Section 6(b)(4) [19] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) [20] of the Act in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In 2019, Commission staff published guidance suggesting the types of information that self-regulatory organizations (''SROs'') may use to demonstrate that their fee filings comply with the standards of the Exchange Act (the ''Staff Guidance'').[21] While the Exchange understands that the Staff Guidance does not create new legal obligations on SROs, the Staff Guidance is consistent with the Exchange's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. The Staff Guidance provides that in assessing the reasonableness of a fee, the Staff would consider whether the fee is constrained by significant competitive forces. To determine whether a proposed fee is constrained by significant competitive forces, the Staff Guidance further provides that the Staff would consider whether the evidence provided by an SRO in a Fee Filing proposal demonstrates (i) that there are reasonable substitutes for the product or service that is the subject of a proposed fee; (ii) that ''platform'' competition constrains the fee; and/or (iii) that the revenue and cost analysis provided by the SRO otherwise demonstrates that the proposed fee would not result in the SRO taking supra-competitive profits.[22] The Exchange provides sufficient evidence below to support the findings that the proposed fees are reasonable because the projected revenue and cost analysis contained herein demonstrates that the proposed fees would not result in the Exchange taking supra-competitive profits.

As noted above, the Exchange also adopted the cToM data feed and expressly waived fees over two years to incentivize market participants to subscribe and make the Exchange's cToM data more widely available.[23] In the five years since the Exchange launched operations and adopted Complex Order functionality, the Exchange has grown its monthly complex market share from 0% to 3.53% of the total electronic complex non-index volume executed on U.S. options exchanges offering complex functionality for the month of January 2024. One of the primary objectives of the Exchange is to provide competition and to reduce fixed costs imposed upon the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

[18] 15 U.S.C. 78f.

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78f(b)(5).

[21] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[22] *Id.*

[23] *See supra* note 15.

Accordingly, in proposing to charge fees for market data, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Members—both generally and in relation to other Members—to ensure the fees will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange does not believe it needs to otherwise address questions about market competition in the context of this filing because the proposed fees are consistent with the Act based on its Cost Analysis. The Exchange also believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[24] and Rule 19b–4 thereunder,[25] with respect to the types of information SROs should provide when filing fee changes, and Section 6(b) of the Act,[26] which requires, among other things, that exchange fees be reasonable and equitably allocated,[27] not designed to permit unfair discrimination,[28] and that they do not impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.[29] This proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.

In 2019, the Exchange completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis'').[30] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers'').

As an initial step, the Exchange determined the total cost for the Exchange and its affiliated markets[31] for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[32] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all cost drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below. For instance, fixed costs that are not driven by client activity (*e.g.,* message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (for example, 61.9% of the data center total expense amount is allocated to 10Gb ULL connectivity), with smaller allocations to ToM and cToM (1.1% combined), and the remainder to the provision of other connectivity, ports, transaction execution, membership services and other market data services (37%). This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below. Each of the below cost allocations is unique to the Exchange

[24] 15 U.S.C. 78s(b)(1).

[25] 17 CFR 240.19b–4.

[26] 15 U.S.C. 78f(b).

[27] 15 U.S.C. 78f(b)(4).

[28] 15 U.S.C. 78f(b)(5).

[29] 15 U.S.C. 78f(b)(8).

[30] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

[31] The affiliated markets include Miami International Securities Exchange, LLC (''MIAX''); separately, the options and equities markets of MIAX PEARL, LLC (''MIAX Pearl''); and MIAX Emerald, LLC (''MIAX Emerald'').

[32] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other cost-justified potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive Cost Analysis, which was again recently further refined, the Exchange analyzed nearly every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of ToM and cToM data feeds, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of ToM and cToM data feeds, and thus bears a relationship that is, ''in nature and closeness,'' directly related to ToM and cToM data feeds. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide ToM and cToM data feeds is $62,626 (the Exchange divided the annual cost for each of ToM and cToM by 12 months, then added both numbers together), as further detailed below.

Costs Related to Offering ToM and cToM Data Feeds

The following chart details the individual line-item (annual) costs considered by the Exchange to be related to offering the ToM and cToM data feeds to its Members and other customers, as well as the percentage of the Exchange's overall costs that such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 2.3% of its overall Human Resources cost to offering ToM and cToM data feeds).

Cost drivers	Allocated annual cost [a]	Allocted monthly cost [b]	% of all
Human Resources	$509,350	$42,446	2.3
Connectivity (external fees, cabling, switches, etc.)	1,011	84	1.1
Internet Services and External Market Data	0.00	0.00	0.0
Data Center	16,624	1,385	1.1
Hardware and Software Maintenance & Licenses	18,958	1,580	1.1
Depreciation	17,853	1,488	0.5
Allocated Shared Expenses	187,711	15,643	2.1
Total	751,507	62,626	2.0

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering ToM and cToM. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated market, MIAX, in its similar proposed fee change for ToM and cToM. This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace. The Exchange provides additional explanation below (including the reason for the deviation) for the significant differences, if any.

The Exchange also notes that expenses included in its 2024 fiscal year budget and this proposal are generally higher than its 2023 fiscal year budget and Cost Analysis included in prior filings. This is due to a number of factors, such as, critical vendors and suppliers increasing costs they charge the Exchange, significant exchange staff headcount increases, increased data center costs from the Exchange's data center providers in multiple locations and facilities, higher technology and communications costs, planned hardware refreshes, and system capacity upgrades that increase depreciation expense. Specifically, with regard to employee compensation, the 2024 fiscal year budget includes additional expenses related to increased headcount and new hires that are needed to support the Exchange as it continues to grow (the Exchange and its affiliated companies are projected to hire over 60 additional staff in 2024). Hardware and software expenses have also increased primarily due to price increases from critical vendors and equipment suppliers. Further, the Exchange budgeted for additional hardware and

software needs to support the Exchange's continued growth and expansion. Depreciation and amortization have likewise increased due to recent and planned refreshes in Exchange hardware and software. This new equipment and software then becomes depreciable, as described below. Data center costs have also increased due the following: the Exchange expanding its footprint within its data center; and the data center vendor increasing the costs it charges the Exchange. Lastly, allocated shared expenses have increased due to the overall budgeted increase in costs from 2023 to 2024 necessary to operate and support the Exchange as described below.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining ToM and cToM data feeds and performance thereof (primarily the Exchange's network infrastructure team, which spends a portion of their time performing functions necessary to provide market data). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to market data. From that portion allocated to the Exchange that applied to market data, the Exchange then allocated a weighted average of 2.1% of each employee's time from the above group to ToM and cToM data feeds (which excludes an allocation for the recently hired Head of Data Services for the Exchange and its affiliates).

The Exchange also allocated Human Resources costs to provide ToM and cToM to a limited subset of personnel with ancillary functions related to establishing and maintaining such market data feeds (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing market data feeds) and then applied a smaller allocation to such employees' time to ToM and cToM (less than 1.6%, which includes an allocation for the Head of Data Services). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to providing ToM and cToM, whether it is a sales person selling a market data feed, finance personnel billing for market data feeds or providing budget analysis, or information security ensuring that such market data feeds are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing market data feeds, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing ToM and cToM data feeds: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated 2.1% of each of their employee's time assigned to the Exchange for ToM and cToM, as stated above. Employees from these departments perform numerous functions to support ToM and cToM data feeds, such as the configuration and maintenance of the hardware necessary to support the ToM and cToM data feeds. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting ToM and cToM data feeds and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support ToM and cToM, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the ToM and cToM related Human Resources costs to the extent that they are involved in overseeing tasks related to providing market data. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, Etc.) [33]

The Connectivity cost driver includes cabling and switches required to generate and disseminate the ToM and cToM data feeds and operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete Member subscriptions to ToM and cToM and the servers used at the Exchange's primary and back-up data centers specifically for the ToM and cToM data feeds. Further, as certain servers are only partially utilized to generate and disseminate the ToM and cToM data feeds, only the percentage of such servers devoted to generating and disseminating the ToM and cToM data feeds was included (*i.e.,* the capacity of such servers allocated to the ToM and cToM data feeds).[34]

[33] This cost driver was titled ''Network Infrastructure'' in prior proposals. The Exchange has updated this section to now be in line with its similar cost analysis and cost driver descriptions for other non-transaction fee filings. *See, e.g.,* Securities Exchange Act Release No. 99475 (February 5, 2024), 89 FR 9223 (February 9, 2024) (SR–EMERALD–2024–03).

[34] The Exchange understands that the Investors Exchange, Inc. (''IEX'') and MEMX LLC (''MEMX'') both allocated a percentage of their servers to the production and dissemination of market data to support proposed market data fees. *See* Securities Exchange Act Release Nos. 94630 (April 7, 2022), 87 FR 21945, at page 21949 (April 13, 2022) (SR–IEX–2022–02) *and* 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04). The Exchange does not have insight into either MEMX's

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. External market data includes fees paid to third parties, including other exchanges, to receive market data. The Exchange allocate any costs associated with internet services or external market data to the ToM and cToM data feeds.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide ToM and cToM in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange does not own the primary data center or the secondary data center, but instead leases space in data centers operated by third parties. As the Data Center costs are primarily for space, power, and cooling of servers, the Exchange allocated 1.1% to the applicable Data Center costs for the ToM and cToM data feeds. The Exchange believes it is reasonable to apply the same proportionate percentage of Data Center costs to that of the Connectivity cost driver.

Hardware and Software Maintenance and Licenses

Hardware and Software Maintenance and Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer the ToM and cToM data feeds.[35] Because the hardware and software license fees are correlated to the servers used by the Exchange, the Exchange again applied an allocation of 1.1% of its costs for Hardware and Software Maintenance and Licenses to the ToM and cToM data feeds. The Exchange notes that this allocation is less than MIAX as MIAX allocated 1.3% of its Hardware and Software Maintenance and License expense to ToM and cToM, while MIAX Emerald allocated 1.1% of its Hardware and Software Maintenance and License expense to ToM and cToM. MIAX's allocation results in a slightly higher dollar amount of $8,000 per year (or approximately $667 per month, when dividing the annual cost difference by 12 months and rounding to the nearest dollar) compared to the annual cost of MIAX Emerald for its Hardware and Software Maintenance and License cost driver. This is because MIAX is in the process of replacing and upgrading various hardware and software used to operate its options trading platform in order to maintain premium network performance, including dissemination of ToM and cToM. At the time of this filing, MIAX is undergoing a major hardware refresh, replacing older hardware with new hardware. This hardware includes servers, network switches, cables, optics, protocol data units, and cabinets, to maintain a state-of-the-art technology platform. Because of the timing of the hardware refresh with the timing of this filing, MIAX has a slightly higher expense than MIAX Emerald.

Depreciation

All physical assets, software, and hardware used to provide ToM and cToM, which also includes assets used for testing and monitoring of Exchange infrastructure to provide market data, were valued at cost, and depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes. The vast majority of the software the Exchange uses for its operations to generate and disseminate the ToM and cToM data feeds has been developed in-house over an extended period. This software development also requires quality assurance and thorough testing to ensure the software works as intended. The Exchange also included in the Depreciation cost driver certain budgeted improvements that the Exchange intends to capitalize and depreciate with respect to ToM and cToM in the near-term. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost was therefore narrowly tailored to depreciation related to ToM and cToM. As noted above, the Exchange allocated 0.5% of its allocated depreciation costs to providing ToM and cToM.

The Exchange notes that this allocation differs from its affiliated market, MIAX, due to a number of factors, such as the age of physical assets and software (*e.g.,* older physical assets and software were previously depreciated and removed from the allocation), or certain system enhancements that required new physical assets and software, thus providing a higher contribution to the depreciated cost. For example, the Exchange notes that the percentages it and its affiliate, MIAX, allocated to the depreciation of software and hardware used to generate and disseminate their respective ToM and cToM data feeds are similar (0.8% for MIAX and 0.5% for MIAX Emerald). However, MIAX's dollar amount is greater than that of MIAX Emerald by approximately $17,000 per year (albeit a relatively small amount of approximately $1,415 per month, when rounding to the nearest dollar). This is due to two primary factors. First, MIAX has undergone a technology refresh since the time MIAX Emerald launched in February 2019, leading to it having more hardware and software that is subject to depreciation. Second, MIAX maintains 24 matching engines while MIAX Emerald maintains only 12 matching engines. This also results in more of MIAX's hardware and software being subject to depreciation than MIAX Emerald's hardware and software due to the greater amount of equipment and software necessary to support the greater number of matching engines on MIAX.

Allocated Shared Expenses

Finally, as with other exchange products and services, a portion of general shared expenses was allocated to the provision of ToM and cToM data feeds. These general shared costs are integral to exchange operations, including its ability to provide ToM and cToM. Costs included in general shared expenses include office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications. Similarly, the cost of paying directors to serve on the Exchange's Board of Directors is also included in the Exchange's general shared expense cost driver.[36] These

or IEX's technology infrastructure or what their determinations were based on. However, the Exchange reviewed its own technology infrastructure and believes based on its design, it is more appropriate for the Exchange to allocate a portion of its Connectivity cost driver to market data based on a percentage of overall cost, not on a per server basis.

[35] This expense may be less than the Exchange's affiliated markets, specifically MIAX. This is because each market may maintain and utilize a different amount of hardware and software based on its market model and infrastructure needs. The Exchange allocated a percentage of the overall cost based on actual amounts of hardware and software utilized by that market, which resulted in different cost allocations and dollar amounts.

[36] The Exchange notes that MEMX allocated a precise amount of 10% of the overall cost for directors in a similar non-transaction fee filing. *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–

Continued

general shared expenses are incurred by the Exchange's parent company, MIH, as a direct result of operating the Exchange and its affiliated markets.

The Exchange employed a process to determine a reasonable percentage to allocate general shared expenses to ToM and cToM pursuant to its multi-layered allocation process. First, general expenses were allocated among the Exchange and affiliated markets as described above. Then, the general shared expense assigned to the Exchange was allocated across core services of the Exchange, including market data. Then, these costs were further allocated to sub-categories within the final categories, *i.e.,* ToM and cToM as sub-categories of market data. In determining the percentage of general shared expenses allocated to market data that ultimately apply to ToM and cToM, the Exchange looked at the percentage allocations of each of the cost drivers and determined a reasonable allocation percentage. The Exchange also held meetings with senior management, department heads, and the Finance Team to determine the proper amount of the shared general expense to allocate to ToM and cToM. The Exchange, therefore, believes it is reasonable to assign an allocation, in the range of allocations for other cost drivers, while continuing to ensure that this expense is only allocated once. Again, the general shared expenses are incurred by the Exchange's parent company as a result of operating the Exchange and its affiliated markets and it is therefore reasonable to allocate a percentage of those expenses to the Exchange and ultimately to specific product offerings such as ToM and cToM.

Again, a portion of all shared expenses were allocated to the Exchange (and its affiliated markets) which, in turn, allocated a portion of that overall allocation to all market data products offered by the Exchange. The Exchange then allocated 2.1% of the portion allocated to market data to ToM and cToM. The Exchange believes this allocation percentage is reasonable because, while the overall dollar amount may be higher than other cost drivers, the 2.1% is based on and in line with the percentage allocations of each of the Exchange's other cost drivers. The percentage allocated to ToM and cToM also reflects its importance to the Exchange's strategy and necessity towards the nature of the Exchange's overall operations, which is to provide a resilient, highly deterministic trading system that relies on faster market data feeds than the Exchange's competitors to maintain premium performance. This allocation reflects the Exchange's focus on providing and maintaining high performance market data services, of which ToM and cToM are main contributors.

The Exchange notes that this allocation differs from its affiliated market, MIAX, due to a number of factors, such as the increase in overall headcount, thus providing a higher contribution on MIAX to the depreciated cost. The Exchange notes that the percentages it and its affiliate, MIAX, allocated to this cost driver are similar (2.5% for MIAX and 2.1% for MIAX Emerald). However, MIAX's dollar amount is greater than that of MIAX Emerald by $38,096 per year (albeit a relatively small amount of approximately $3,174 per month, when rounding to the nearest dollar). This is due primarily to significant exchange staff headcount increases.[37] As mentioned above, the 2024 fiscal year budget includes additional expenses related to increased headcount and new hires that are needed to support the Exchange as it continues to grow (with a projected 60 additional staff in 2024). Lastly, allocated shared expenses have increased due to the overall budgeted increase in costs from 2023 to 2024 necessary to operate and support the Exchange and its affiliated markets.

* * * * *

Approximate Cost for ToM and cToM per Month

After determining the approximate allocated monthly cost related to ToM and cToM combined, the total monthly cost for ToM and cToM of $62,626 was divided by the number of total subscribers to ToM and cToM that the Exchange maintained in August 2023 (29 Internal Distributors + 5 External Distributors = 34 total Distributors),[38] to arrive at a cost of approximately $1,842 per month per subscription (rounded to the nearest dollar). Due to the nature of this particular cost, this allocation methodology results in an allocation among the Exchange and its affiliated markets based on set quantifiable criteria, *i.e.,* actual number of ToM and cToM subscribers.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service (including market data) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filings the Exchange recently submitted proposing fees for certain connectivity and ports offered by the Exchange. For instance, in calculating the Human Resources expenses to be allocated to market data based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a commensurate percentage of the cost of such personnel (5.9%) given their focus on functions necessary to provide market data. The salaries of those same personnel were allocated only 2.1% to ToM and cToM and the remaining 97.9% was allocated to other market data products offered by the Exchange (MOR, AIS, etc.), connectivity services, port services, transaction services, and membership services. The Exchange did not allocate any other Human Resources expense for providing market data to any other employee group, outside of a smaller allocation of 1.6% for ToM and cToM of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel.

In total, the Exchange allocated 2.3% of its personnel costs (Human Resources) to providing ToM and cToM. In turn, the Exchange allocated the remaining 97.7% of its Human Resources expense to membership services, transaction services, connectivity services, port services and other market data products. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not

MEMX–2023–04). The Exchange does not calculate is expenses at that granular a level. Instead, director costs are included as part of the overall general allocation.

[37] The Exchange notes that this reference to increased headcount is used here to explain why MIAX's dollar amount of its allocated shared expense is greater than that of MIAX Emerald. A similar reference is not included in the above discussion of the Human Resources cost driver because the description of that cost driver does not include a similar comparison.

[38] The used August 2023 subscription data because that was the last full month the fees proposed herein for ToM and cToM were charged, before the Exchange's prior filing to adopt the same fees was suspended by the Commission. *See supra* note 12. While there has been no material overall change to the number of subscriptions since August 2023, the Exchange notes that the number of subscriptions may fluctuate and demand may change when fees are removed and reinstated. Accordingly, the Exchange believes that, in order to obtain an accurate measure of actual demand for fee-liable subscriptions, the Exchange looked to the last month that the fees were in place prior to suspension, which was August 2023.

double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including market data, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide ToM and cToM data feeds to its Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing ToM and cToM, but instead allocated approximately 0.5% of the Exchange's overall depreciation and amortization expense to ToM and cToM combined. The Exchange allocated the remaining depreciation and amortization expense (99.5%) toward the cost of providing transaction services, membership services, connectivity services, port services, and other market data products.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from ToM and cToM, the Exchange will have to be successful in retaining existing clients that wish to maintain subscriptions to those market data feeds or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of market data services it will receive additional revenue to offset future cost increases. However, if use of market data services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [39]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with creating, generating, and disseminating the ToM and cToM data feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.). The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for market data subscribers. Subscribers, particularly those of ToM and cToM, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide ToM and cToM will equal $751,507. Based on current ToM and cToM subscribers, the Exchange would generate annual revenue of approximately $872,880 for ToM and cToM combined.[40] The Exchange believes this represents a modest profit of 13.9% when compared to the cost of providing ToM and cToM data feeds.

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing ToM and cToM data feeds versus the total projected revenue of the Exchange associated with ToM and cToM.

The Exchange also notes that the resultant profit margin differs slightly from the profit margins set forth in a similar fee filing by its affiliated market, MIAX. This is not atypical among exchanges and is due to a number of factors that differ between these two markets, including: different market models, market structures, and product offerings (price-time, pro-rata, simple, and complex); different pricing models; different number of market participants and connectivity subscribers; different maintenance and operations costs, as described in the cost allocation methodology above; different technical architecture (*e.g.,* the number of matching engines per exchange, *i.e.,* MIAX maintains 24 matching engines while MIAX Emerald maintains only 12 matching engines); and different maturity phase of MIAX and its affiliated markets (*i.e.,* start-up versus growth versus more mature). All of these factors contribute to a unique and differing level of profit margin per exchange.

Further, MIAX and MIAX Emerald propose to charge the same rates for their respective ToM and cToM data feeds, which are comparable to, or lower than, similar fees for similar products

[39] For purposes of calculating projected annualized 2024 revenue for ToM and cToM, the Exchange used monthly revenues for August 2023, the last month the Exchange billed at the proposed rates before the Commission suspended the earlier filing. *Id.*

[40] The Exchange notes that the total revenue number of $872,880 does not equal the full monthly fee multiplied by the total number of Distributors, due to a new Distributor first purchasing a ToM and cToM data feed mid-month and having their first month's fee(s) pro-rated for External Distribution, pursuant to Section 6)a) of the Exchange Fee Schedule.

charged by competing exchanges. For example, for Internal Distributors of ToM and cToM, the Exchange proposes a lower fee than the fee charged by ISE for ISE's Top Quote Feed ($2,000 for the Exchange vs. $3,000 for ISE).[41] NYSE Arca charges even higher fees for the NYSE Arca Options Top Feed than the Exchange's proposed fees ($2,000 for the Exchange vs. $3,000 per month plus an additional $2,000 for redistribution on NYSE Arca).[42] Accordingly, the Exchange believes that comparable and competitive pricing are key factors in determining whether a proposed fee meets the requirements of the Act, regardless of whether that same fee across the Exchange's affiliated markets leads to slightly different profit margins due to factors outside of the Exchange's control (*i.e.,* more subscribers to ToM and/or cToM on MIAX or MIAX Emerald and vice versa).

The Exchange also reiterates that prior to July of 2021, the month in which it first proposed to adopt fees for cToM, the Exchange did not charge any fees for cToM and its allocation of costs to cToM was part of a holistic allocation that also allocated costs to other core services without double-counting any expenses. The Exchange is owned by a holding company that is the parent company of four exchange markets and, therefore, the Exchange and its affiliated markets must allocate shared costs across all of those markets accordingly, pursuant to the above-described allocation methodology. In contrast, IEX and MEMX, which are currently each operating only one exchange, in their recent non-transaction fee filings allocate the entire amount of that same cost to a single exchange. This can result in lower profit margins for the non-transaction fees proposed by IEX and MEMX because the single allocated cost does not experience the efficiencies and synergies that result from sharing costs across multiple platforms.[43] The Exchange and its affiliated markets often share a single cost, which results in cost efficiencies that can cause a broader gap between the allocated cost amount and projected revenue, even though the fee levels being proposed are lower or competitive with competing markets (as described above). To the extent that the application of a cost-based standard results in Commission Staff making determinations as to the appropriateness of certain profit margins, the Commission Staff should consider whether the proposed fee level is comparable to, or competitive with, the same fee charged by competing exchanges and how different cost allocation methodologies (such as across multiple markets) may result in different profit margins for comparable fee levels. If Commission Staff is making determinations as to appropriate profit margins, the Exchange believes that the Commission should be clear to all market participants as to what they have determined is an appropriate profit margin and should apply such determinations consistently and, in the case of certain legacy exchanges, retroactively, if such standards are to avoid having a discriminatory effect. Further, the proposal reflects the Exchange's efforts to control its costs, which the Exchange does on an ongoing basis as a matter of good business practice. A potential profit margin should not be judged alone based on its size, but is also indicative of costs management and whether the ultimate fee reflects the value of the services provided. For example, a profit margin on one exchange should not be deemed excessive where that exchange has been successful in controlling its costs, but not excessive where on another exchange where that exchange is charging comparable fees but has a lower profit margin due to higher costs. Doing so could have the perverse effect of not incentivizing cost control where higher costs alone are used to justify fees increases.

Accordingly, while the Exchange is supportive of transparency around costs and potential margins (applied across all exchanges), as well as periodic review of revenues and applicable costs (as discussed below), the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning—or seeking to earn—supra-competitive profits, the standard set forth in the Staff Guidance. The Exchange believes the Cost Analysis and related projections in this filing demonstrate this fact.

Reasonableness

Overall. With regard to reasonableness, the Exchange understands that the Commission has traditionally taken a market-based approach to examine whether the exchange making the fee proposal was subject to significant competitive forces in setting the terms of the proposal. The Exchange understands that in general the analysis considers whether the exchange has demonstrated in its filing that (i) there are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the exchange taking supra-competitive profits. If the exchange demonstrates that the fee is subject to significant competitive forces, the Exchange understands that in general the analysis will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. The Exchange further understands that if the filing fails to demonstrate that the fee is constrained by competitive forces, the exchange must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

The Exchange has not determined its proposed overall market data fees based on assumptions about market competition, instead relying upon a cost-plus model to determine a reasonable fee structure that is informed by the Exchange's understanding of different uses of the products by different types of participants. In this context, the Exchange believes the proposed fees overall are fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for the Exchange's aggregate costs

[41] *See* ISE Options 7 Pricing Schedule, Section 10, H., *available at Https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207* (assessing Professional internal and external distributors $3,000 per month, plus $20 per month per controlled device for ISE's Top Quote Feed).

[42] Fees for the NYSE Arca Options Top Feed, which is the comparable product to ToM, are $3,000 per month for access (internal use) and an additional $2,000 per month for redistribution (external distribution), compared to the Exchange's proposed fees of $2,000 and $3,000 for Internal and External Distributors, respectively. In addition, for its NYSE Arca Options Top Feed, NYSE Arca charges for three different categories of non-display usage, and user fees, both of which the Exchange does not propose to charge, causing the overall cost of NYSE Arca Options Top Feed to far exceed the Exchange's proposed rates. *See* NYSE Arca Options Proprietary Market Data Fees, *available at: Https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Options_Proprietary_Data_Fee_Schedule.pdf.*

[43] The Exchange acknowledges that IEX included in its proposal to adopt market data fees after offering market data for free an analysis of what its projected revenue would be if all of its existing customers continued to subscribe versus what its projected revenue would be if a limited number of customers subscribed due to the new fees. *See* Securities Exchange Act Release No. 94630 (April 7, 2022), 87 FR 21945 (April 13, 2022) (SR–IEX–2022–02). MEMX did not include a similar analysis in either of its recent non-transaction fee proposals. *See, e.g., supra* note 34. The Exchange does not believe a similar analysis would be useful here because it is amending existing fees, not proposing to charge a new fee where existing subscribers may terminate connections because they are no longer enjoying the service at no cost.

of offering the ToM and cToM data feeds. The Exchange believes the proposed fees are reasonable because they are designed to generate annual revenue to recoup some or all of Exchange's annual costs of providing ToM and cToM data with a reasonable mark-up. As discussed in the Purpose section, the Exchange estimates this fee filing will result in annual revenue of approximately $872,880, representing a potential mark-up of just 13.9% over the cost of providing ToM and cToM data. Accordingly, the Exchange believes that this fee methodology is reasonable because it allows the Exchange to recoup all of its expenses for providing the ToM and cToM data products (with any additional revenue representing no more than what the Exchange believes to be a reasonable rate of return). The Exchange also believes that the proposed fees are reasonable because they are generally less than the fees charged by competing options exchanges for comparable market data products, notwithstanding that the competing exchanges may have different system architectures that may result in different cost structures for the provision of market data.

The Exchange believes the proposed fees for the ToM and cToM data feeds are reasonable when compared to fees for comparable products, compared to which the Exchange's proposed fees are generally lower, as well as other comparable data feeds priced significantly higher than the Exchange's proposed fees for the ToM and cToM data feeds.

Internal Distribution Fees. The Exchange believes that it is reasonable to charge fees to access the ToM and cToM data feeds for Internal Distribution because of the value of such data to subscribers in their profit-generating activities. The Exchange also believes that the proposed monthly Internal Distribution fee for cToM is reasonable as it is similar to the amount charged by at least one other exchange of comparable size for comparable data products, and lower than the fees charged by other exchange for comparable data products.[44]

External Distribution Fees. The Exchange believes that it is reasonable to charge External Distribution fees for the ToM and cToM data feeds because vendors receive value from redistributing the data in their business products provided to their customers. The Exchange believes that charging External Distribution fees is reasonable because the vendors that would be charged such fees profit by re-transmitting the Exchange's market data to their customers. These fees would be charged only once per month to each vendor account that redistributes any ToM and cToM data feeds, regardless of the number of customers to which that vendor redistributes the data.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the ToM and cToM data feeds are reasonable.

Equitable Allocation

Overall. The Exchange believes that its proposed fees are reasonable, fair, and equitable, and not unfairly discriminatory because they are designed to align fees with services provided. The Exchange believes the proposed fees for the ToM and cToM data feeds are allocated fairly and equitably among the various categories of users of the feeds, and any differences among categories of users are justified and appropriate.

The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the ToM and cToM data feeds. Any subscriber or vendor that chooses to subscribe to the ToM and cToM data feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or more ToM and cToM data feeds is based on objective differences in usage of ToM and cToM data feeds among different Members, which are still ultimately in the control of any particular Member. The Exchange believes the proposed pricing of the ToM and cToM data feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed and the value of that information to market participants.

Internal Distribution Fees. The Exchange believes the proposed monthly fees for Internal Distribution of the ToM and cToM data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the ToM and cToM data feeds for internal distribution, regardless of what type of business they operate.

External Distribution Fees. The Exchange believes the proposed monthly fees for External Distribution of the ToM and cToM data feeds are equitably allocated and not unfairly discriminatory because they would be charged on an equal basis to all data recipients that receive the ToM and cToM data feeds that choose to redistribute the feeds externally, regardless of what business they operate. The Exchange also believes that the proposed monthly fees for External Distribution are equitably allocated when compared to lower proposed fees for Internal Distribution because data recipients that are externally distributing ToM and cToM data feeds are able to monetize such distribution and spread such costs amongst multiple third party data recipients, whereas the Internal Distribution fee is applicable to use by a single data recipient (and its affiliates).

The Exchange believes that it is reasonable, equitable and not unfairly discriminatory to assess Internal Distributors fees that are less than the fees assessed for External Distributors for subscriptions to the ToM and cToM data feeds because Internal Distributors have limited, restricted usage rights to the market data, as compared to External Distributors, which have more expansive usage rights. All Members and non-Members that decide to receive any market data feed of the Exchange (or its affiliates, MIAX Pearl and MIAX), must first execute, among other things, the MIAX Exchange Group Exchange Data Agreement (the ''Exchange Data Agreement'').[45] Pursuant to the Exchange Data Agreement, Internal Distributors are restricted to the ''internal use'' of any market data they receive. This means that Internal Distributors may only distribute the Exchange's market data to the recipient's officers and employees and its affiliates.[46] External Distributors may distribute the Exchange's market data to persons who are not officers, employees or affiliates of the External Distributor,[47] and may charge their own fees for the redistribution of such market data. External Distributors may monetize their receipt of the ToM and cToM data feeds by charging their customers fees for receipt of the Exchange's ToM and cToM data. Internal Distributors do not have the same ability to monetize the Exchange's ToM and cToM data feeds. Accordingly, the Exchange believes it is fair, reasonable and not unfairly discriminatory to assess External Distributors a higher fee for the Exchange's ToM and cToM data feeds as External Distributors have greater usage rights to commercialize such market data and can adjust their own fee structures if necessary.

The Exchange also utilizes more resources to support External

[44] *See supra* notes 41 and 42.

[45] *See* Exchange Data Agreement, *available at https://www.miaxglobal.com/markets/us-options/all-options/market-data-vendor-agreements.*

[46] *See id.*

[47] *See id.*

Distributors versus Internal Distributors, as External Distributors have reporting and monitoring obligations that Internal Distributors do not have, thus requiring additional time and effort of Exchange staff. For example, External Distributors have monthly reporting requirements under the Exchange's Market Data Policies.[48] Exchange staff must then, in turn, process and review information reported by External Distributors to ensure the External Distributors are redistributing cToM data in compliance with the Exchange's Market Data Agreement and Policies.

The Exchange believes the proposed cToM fees are equitable and not unfairly discriminatory because the fee level results in a reasonable and equitable allocation of fees amongst subscribers for similar services, depending on whether the subscriber is an Internal or External Distributor. Moreover, the decision as to whether or not to purchase market data is entirely optional to all market participants. Potential purchasers are not required to purchase the market data, and the Exchange is not required to make the market data available. Purchasers may request the data at any time or may decline to purchase such data. The allocation of fees among users is fair and reasonable because, if market participants decide not to subscribe to the data feed, firms can discontinue their use of the cToM data.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the ToM and cToM data feeds are equitably allocated.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[49] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed fees place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of the data feed by each market participant based on whether the market participant internally or externally distributes the Exchange data, which are still ultimately in the control of any particular Member, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of data consumed by various market participants and their usage thereof.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other exchanges that is not necessary or appropriate. In particular, market participants are not forced to subscribe to either data feed, as described above. Additionally, other exchanges have similar market data fees with comparable rates in place for their participants.[50] The proposed fees are based on actual costs and are designed to enable the Exchange to recoup its applicable costs with the possibility of a reasonable profit on its investment as described in the Purpose and Statutory Basis sections. Competing exchanges are free to adopt comparable fee structures subject to the Commission's rule filing process. Allowing the Exchange, or any new market entrant, to waive fees (as the Exchange did for cToM) for a period of time to allow it to become established encourages market entry and thereby ultimately promotes competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[51] and Rule 19b–4(f)(2)[52] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–EMERALD–2024–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–EMERALD–2024–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–EMERALD–2024–15 and should be submitted on or before May 23, 2024.

[48] *See* Section 6 of the Exchange's Market Data Policies, *available at Https://www.miaxglobal.com/sites/default/files/page-files/MIAX_Exchange_Group_Market_Data_Policies_07202021.pdf.*

[49] 15 U.S.C. 78f(b)(8).

[50] *See supra* notes 41 and 42.

[51] 15 U.S.C. 78s(b)(3)(A)(ii).

[52] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09477 Filed 5–1–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100039; File No. SR–EMERALD–2024–14]

Self-Regulatory Organizations; MIAX Emerald LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule for Purge Ports

April 26, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 15, 2024, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Emerald Options Exchange Fee Schedule (the ''Fee Schedule'') to amend fees for Purge Ports.[3]

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/emerald-options/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the fees for Purge Ports, which is a function enabling Market Makers [4] to cancel all open quotes or a subset of open quotes through a single cancel message. The Exchange currently provides Market Makers the option to purchase Purge Ports to assist in their quoting activity. Purge Ports provide Market Makers with the ability to send purge messages to the Exchange System.[5] Purge Ports are not capable of sending or receiving any other type of messages or information. The use of Purge Ports is completely optional and no rule or regulation requires that a Market Maker utilize them.

The Exchange initially filed the proposal on September 29, 2023 (the ''Initial Proposal'').[6] On November 22, 2023, the Exchange withdrew the Initial Proposal and replaced with a revised filing (the ''Second Proposal'').[7] On January 17, 2024, the Exchange withdrew the Second Proposal and, on January 31, 2024, replaced it with a further revised filing (the ''Third Proposal'').[8] On March 8, 2024, the Exchange withdrew the Third Proposal and replaced it with a further revised filing (the ''Fourth Proposal'').[9] On April 15, 2024, the Exchange withdrew the Fourth Proposal and replaced it with a further revised filing (the ''Fifth Proposal'').

The Exchange is including a cost analysis in this filing to justify the proposed fees. As described more fully below, the cost analysis includes, among other things, descriptions of how the Exchange allocated costs among it and its affiliated exchanges for similar proposed fee changes (separately between MIAX Pearl Options [10] and MIAX,[11] collectively referred to herein as the ''affiliated markets''), to ensure no cost was allocated more than once, as well as detail supporting its cost allocation processes and explanations as to why a cost allocation in this proposal may differ from the same cost allocation in similar proposals submitted by the affiliated markets. The proposed fees are intended to cover the Exchange's cost of providing Purge Ports with a reasonable mark-up over those costs.

Purge Port Fee Change

Unlike other options exchanges that charge fees for Purge Ports on a per port basis,[12] the Exchange assesses a flat fee of $1,500 per month, regardless of the number of Purge Ports utilized by a Market Maker. Prior to the Initial Proposal, a Market Maker could request and be allocated two (2) Purge Ports per Matching Engine [13] to which it connects and not all Market Makers connected to all of the Exchange's Matching Engines.

The Exchange now proposes to amend the fee for Purge Ports to align more closely with other exchanges who charge on a per port basis by providing two (2) Purge Ports per Matching Engine for a monthly flat fee of $600 per month per Matching Engine. The only difference with a per port structure is that Market Makers receive two (2) Purge Ports per Matching Engine for the

[53] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The proposed fee change is based on a recent proposal by Nasdaq Phlx LLC (''Phlx'') to adopt fees for purge ports. *See* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[4] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* Exchange Rule 100.

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[6] *See* Securities Exchange Act Release No. 98734 (October 12, 2023), 88 FR 71894 (October 18, 2023) (SR–EMERALD–2023–26).

[7] *See* Securities Exchange Act Release No. 99089 (December 5, 2023), 88 FR 85941 (December 11, 2023) (SR–EMERALD–2023–29).

[8] *See* Securities Exchange Act Release No. 99529 (February 13, 2024), 89 FR 12907 (February 20, 2024) (SR–EMERALD–2024–05).

[9] *See* Securities Exchange Act Release No. 99812 (March 20, 2024), 89 FR 21080 (March 26, 2024) (SR–EMERALD–2024–11).

[10] MIAX Pearl Options is the options market of MIAX PEARL, LLC (''MIAX Pearl''), which also operates an equities trading facility called MIAX Pearl Equities. *See* Exchange Rule 100 and MIAX Pearl Rule 1901.

[11] The term ''MIAX'' means Miami International Securities Exchange, LLC. *See* Exchange Rule 100.

[12] *See* Cboe BXZ Exchange, Inc. (''BZX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe EDGX Exchange, Inc. (''EDGX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe Exchange, Inc. (''Cboe'') Fee Schedule ($850 per purge port per month). *See also* Nasdaq GEMX, Options 7, Pricing Schedule, Section 6.C.(3). Nasdaq GEMX, LLC (''Nasdaq GEMX'') assesses its members $1,250 per SQF Purge Port per month, subject to a monthly cap of $17,500 for SQF Purge Ports and SQF Ports, applicable to market makers. *See also* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[13] A Matching Engine is a part of the Exchange's electronic system that processes options quotes and trades on a symbol-by-symbol basis. Some matching engines will process option classes with multiple root symbols, and other matching engines will be dedicated to one single option root symbol (for example, options on SPY will be processed by one single matching engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated matching engine. A particular root symbol may not be assigned to multiple matching engines. *See* the Definitions Section of the Fee Schedule.

same proposed monthly fee, rather than being charged a separate fee for each Purge Port. The Exchange proposes to charge the proposed fee for Purge Ports per Matching Engine, instead on a per Purge Port basis, due to its System architecture which provides two (2) Purge Ports per Matching Engine for redundancy purposes. In addition, the proposed fee is lower than the comparable fee charged by competing exchanges that also charge on a per port basis, notwithstanding that the Exchange is providing up to two (2) Purge Ports for that same lower fee.[14] Other exchanges may also maintain a different number of matching engines within their architecture than the Exchange (*i.e.,* MIAX maintains twenty-four (24) matching engines, MIAX Pearl Options maintains twelve (12) matching engines, and MIAX Emerald maintains twelve (12) matching engines).

Similar to a per port charge, Market Makers are able to select the Matching Engines that they want to connect to,[15] based on the business needs of each Market Maker, and pay the applicable fee based on the number of Matching Engines and ports utilized. The Exchange believes that the proposed fee provides Market Makers with flexibility to control their Purge Port costs based on the number of Matching Engines each Marker Maker elects to connect to based on each Market Maker's business needs.

* * * * *

A logical port represents a port established by the Exchange within the Exchange's System for trading and billing purposes. Each logical port grants a Member [16] the ability to accomplish a specific function, such as order entry, order cancellation, access to execution reports, and other administrative information.

Purge Ports are designed to assist Market Makers [17] in the management of, and risk control over, their quotes, particularly if the firm is dealing with a large number of securities. For example, if a Market Maker detects market indications that may influence the execution potential of their quotes, the Market Maker may use Purge Ports to reduce uncertainty and to manage risk by purging all quotes in a number of securities. This allows Market Makers to seamlessly avoid unintended executions, while continuing to evaluate the market, their positions, and their risk levels. Purge Ports are used by Market Makers that conduct business activity that exposes them to a large amount of risk across a number of securities. Purge Ports enable Market Makers to cancel all open quotes, or a subset of open quotes through a single cancel message. The Exchange notes that Purge Ports increase efficiency of already existing functionality enabling the cancellation of quotes.

The Exchange operates highly performant systems with significant throughput and determinism which allows participants to enter, update and cancel quotes at high rates. Market Makers may currently cancel individual quotes through the existing functionality, such as through the use of a mass cancel message by which a Market Maker may request that the Exchange remove all or a subset of its quotations and block all or a subset of its new inbound quotations.[18] Other than Purge Ports being a dedicated line for cancelling quotations, Purge Ports operate in the same manner as a mass cancel message being sent over a different type of port. For example, like Purge Ports, mass cancellations sent over a logical port may be done at either the firm or MPID level. As a result, Market Makers can currently cancel quotes in rapid succession across their existing logical ports [19] or through a single cancel message, all open quotes or a subset of open quotes.

Similarly, Market Makers may also use cancel-on-disconnect control when they experience a disruption in connection to the Exchange to automatically cancel all quotes, as configured or instructed by the Member or Market Maker.[20] In addition, the Exchange already provides similar ability to mass cancel quotes through the Exchange's risk controls, which are offered at no charge and enables Market Makers to establish pre-determined levels of risk exposure, and can be used to cancel all open quotes.[21] Accordingly, the Exchange believes that the Purge Ports provide an efficient option as an alternative to already available services and enhance the Market Maker's ability to manage their risk.

The Exchange believes that market participants benefit from a dedicated purge mechanism for specific Market Makers and to the market as a whole. Market Makers will have the benefit of efficient risk management and purge tools. The market will benefit from potential increased quoting and liquidity as Market Makers may use Purge Ports to manage their risk more robustly. Only Market Makers that request Purge Ports would be subject to the proposed fees, and other Market Makers can continue to operate in exactly the same manner as they do today without dedicated Purge Ports, but with the additional purging capabilities described above.

Implementation Date

The proposed fee change is immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed fee is consistent with Section 6(b)(4) of the Act [24] because it represents an equitable allocation of reasonable dues, fees and other charges among market participants.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

In proposing to charge fees for port services, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Members—both generally and in

[14] *See supra* note 12.

[15] The Exchange notes that each Matching Engine corresponds to a specified group of symbols. Certain Market Makers choose to only quote in certain symbols while other Market Makers choose to quote the entire market.

[16] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[17] Members seeking to become registered as a Market Maker must comply with the applicable requirements of Chapter VI of the Exchange's Rules.

[18] *See* Exchange Rule 519C(a) and (b).

[19] Current Exchange port functionality supports cancelation rates that exceed one thousand messages per second and the Exchange's research indicates that certain market participants rely on such functionality and at times utilize such cancelation rates.

[20] *See* Exchange Rule 519C (c).

[21] *See* Exchange Rule 532.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(4).

relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[25] and Rule 19b–4 thereunder,[26] with respect to the types of information exchanges should provide when filing fee changes, and Section 6(b) of the Act,[27] which requires, among other things, that exchange fees be reasonable and equitably allocated,[28] not designed to permit unfair discrimination,[29] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[30] The Exchange notes that the legacy exchanges with whom the Exchange vigorously competes for order flow and market share, were not subject to any such diligence or transparency in setting their baseline non-transaction fees, most of which were put in place before the Staff Guidance.[31]

As detailed below, the Exchange recently calculated its aggregate annual costs for providing Purge Ports to be $822,969 (or approximately $68,581 per month, rounded to the nearest dollar when dividing the annual cost by 12 months). In order to cover the aggregate costs of providing Purge Ports to its Market Makers going forward and to make a modest profit, as described below, the Exchange proposes to modify its Fee Schedule to charge a fee of $600 per Matching Engine for Purge Ports.

In 2019, the Exchange completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis'').[32] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk and purge functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers''). The Exchange recently update its Cost Analysis using its 2024 estimated budget as described below.

As an initial step, the Exchange determined the total cost for the Exchange and the affiliated markets for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[33] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all costs drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below.

This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below. Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can

[25] 15 U.S.C. 78s(b)(1).

[26] 17 CFR 240.19b–4.

[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(4).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(8).

[31] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees* (the ''Staff Guidance'').

[32] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

[33] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive updated Cost Analysis, which was again recently further refined, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of connectivity and port services, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of Purge Port services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to Purge Port services. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide Purge Port services is $68,581, as further detailed below.

Costs Related to Offering Purge Ports

The following chart details the individual line-item costs considered by the Exchange to be related to offering Purge Ports as well as the percentage of the Exchange's overall costs that such costs represent for each cost driver (*e.g.,* as set forth below, the Exchange allocated approximately 2.2% of its overall Human Resources cost to offering Purge Ports).

Cost drivers	Allocated annual cost [a]	Allocated monthly cost [b]	% of all
Human Resources	$491,123	$40,927	2.2
Connectivity (external fees, cabling, switches, etc.)	868	72	0.9
Internet Services and External Market Data	4,914	410	0.9
Data Center	20,379	1,698	1.3
Hardware and Software Maintenance and Licenses	16,268	1,356	0.9
Depreciation	36,917	3,076	1.0
Allocated Shared Expenses	252,500	21,042	2.9
Total	822,969	68,581	2.1

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering Purge Ports. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated markets in their similar proposed fee changes for Purge Ports. This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace. The Exchange provides additional explanation below (including the reason for the deviation) for the significant differences.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining Purge Ports and performance thereof (primarily the Exchange's network infrastructure team, which spends most of their time performing functions necessary to provide port and connectivity services). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the

Exchange is then allocated to port services. From that portion allocated to the Exchange that applied to ports, the Exchange then allocated a weighted average of 2.6% of each employee's time from the above group to Purge Ports.

The Exchange also allocated Human Resources costs to provide Purge Ports to a limited subset of personnel with ancillary functions related to establishing and maintaining such ports (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing Purge Ports) and then applied a smaller allocation to such employees' time to Purge Ports (1.3%). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to Purge Ports, whether it is a sales person selling port services, finance personnel billing for port services or providing budget analysis, or information security ensuring that such ports are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing Purge Ports, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing Purge Ports: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated 2.6% of each of their employee's time assigned to the Exchange for Purge Ports, as stated above. Employees from these departments perform numerous functions to support Purge Ports, such as the installation, re-location, configuration, and maintenance of Purge Ports and the hardware they access. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting Purge Ports and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support Purge Ports, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the Purge Ports related Human Resources costs to the extent that they are involved in overseeing tasks related to providing Purge Ports. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, Etc.)

The Connectivity cost driver includes external fees paid to connect to other exchanges and third parties, cabling and switches required to operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete connections to the Exchange and to connect to external markets. The Exchange notes that its connectivity to external markets vendors is required in order to receive market data to run the Exchange's matching engine and basic operations compliant with existing regulations, primarily Regulation NMS.

The Exchange relies on various connectivity providers for connectivity to the entire U.S. options industry, and infrastructure services for critical components of the network that are necessary to provide and maintain its System Networks and access to its System Networks via 10Gb ULL connectivity. Specifically, the Exchange utilizes connectivity providers to connect to other national securities exchanges and the Options Price Reporting Authority (''OPRA''). The Exchange understands that these service providers provide services to most, if not all, of the other U.S. exchanges and other market participants. Connectivity provided by these service providers is critical to the Exchanges daily operations and performance of its System Networks which includes Purge Ports. Without these services providers, the Exchange would not be able to connect to other national securities exchanges, market data providers or OPRA and, therefore, would not be able to operate and support its System Networks, including Purge Ports. In addition, the connectivity is necessary for the Exchange to notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Also, like other types of ports offered by the Exchange, Purge Ports leverage the Exchange's existing 10Gb ULL connectivity, which also relies on connectivity to other national securities exchanges and OPRA. The Exchange does not employ a separate fee to cover its connectivity provider expense and recoups that expense, in part, by charging for Purge Ports.

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. For purposes of Purge Ports, the Exchange also includes a portion of its costs related to external market data. External market data includes fees paid to third parties, including OPRA, to receive and consume market data from other markets. The Exchange includes external market data costs towards Purge Ports because such market data is necessary to offer certain services related to such ports, such as checking for market conditions (*e.g.,* halted securities). External market data is also consumed at the Matching Engine level for, among other things, validating quotes on entry against the national best bid or offer (''NBBO'').[34] Purge Ports are a component of the Matching Engine, and used by market participants to cancel multiple resting quotes within the Matching Engine. While resting, the Exchange uses external market data to manage those quotes, such as preventing trade-throughs, and those quotes are also reported to OPRA for inclusion in this consolidated data stream. The Exchange also must notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Thus, since market data from other exchanges is consumed by the Matching Engine to validate quotes and check market conditions, the Exchange

[34] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

believes it is reasonable to allocate a small amount of such costs to Purge Ports.

For the reasons set forth above, the Exchange believes it is reasonable to allocate a small amount of such costs to Purge Ports since market data from other exchanges is consumed at the Exchange's Purge Port level to validate purge messages and the necessity to cancel a resting quote via a purge message or via some other means.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide Purge Ports in the third-party data centers where it maintains its equipment as well as related costs for market data to then enter the Exchange's System. The Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third-parties. The Exchange has allocated a percentage of its Data Center cost (1.3%) to Purge Ports because the third-party data centers and the Exchange's physical equipment contained therein are necessary for providing Purge Ports. In other words, for the Exchange to operate in a dedicated physical space with direct connectivity by market participants to its trading platform, the data centers are a critical component to the provision of Purge Ports. If the Exchange did not maintain such a presence, then Purge Ports would be of little value to market participants.

Hardware and Software Maintenance and Licenses

Hardware and Software Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer Purge Ports for each Matching Engine of the Exchange. This hardware includes servers, network switches, cables, optics, protocol data units, and cabinets, to maintain a state-of-the-art technology platform. Without hardware and software licenses, Purge Ports would not be able to be offered to market participants because hardware and software are necessary to operate the Exchange's Matching Engines, which are necessary to enable the purging of quotes. The Exchange also routinely works to improve the performance of the hardware and software used to operate the Exchange's network and System. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to allocate a certain percentage of its hardware and software expense to help offset those costs of providing Purge Port connectivity to its Matching Engines.

Depreciation

The vast majority of the software the Exchange uses to provide Ports has been developed in-house and the cost of such development, which takes place over an extended period of time and includes not just development work, but also quality assurance and testing to ensure the software works as intended, is depreciated over time once the software is activated in the production environment. Hardware used to provide Purge Ports includes equipment used for testing and monitoring of order entry infrastructure and other physical equipment the Exchange purchased and is also depreciated over time.

All hardware and software, which also includes assets used for testing and monitoring of order entry infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. The Exchange allocated 1.0% of all depreciation costs to providing Purge Ports. The Exchange allocated depreciation costs for depreciated software necessary to operate the Exchange because such software is related to the provision of Purge Ports. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost driver was therefore narrowly tailored to depreciation related to Purge Ports.

Allocated Shared Expenses

Finally, a portion of general shared expenses was allocated to overall Purge Port costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide Purge Ports. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange again notes that the cost of paying directors to serve on its Board of Directors is included in the calculation of Allocated Shared Expenses, and thus a portion of such overall cost amounting to less than 3% of the overall cost for directors was allocated to providing Purge Ports.

Approximate Cost for Purge Ports per Month

Based on projected 2024 data, the total monthly cost allocated to Purge Ports of $68,581 was divided by the total number of Matching Engines in which Market Makers used Purge Ports for the month of December 2023, which was 132, resulting in an approximate cost of $522 per Matching Engine per month for Purge Port usage (when rounding to the nearest dollar). The Exchange notes that the flat fee of $600 per month per Matching Engine entitles each Market Maker to two Purge Ports per Matching Engine. The majority of Market Makers are connected to all twenty-four of the Exchange's Matching Engines and utilize Purge Ports on each Matching Engine, except one Market Maker, which only utilizes Purge Ports on three Matching Engines.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core services (including Purge Ports) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal. For instance, in calculating the Human Resources expenses to be allocated to Purge Ports based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a higher percentage of the cost of such personnel (19.3%) given their focus on functions necessary to provide Ports. The salaries of those same personnel were allocated only 2.6% to Purge Ports and the remaining 97.4% was allocated to connectivity, other port services, transaction services, membership services and market data. The Exchange did not allocate any other Human Resources expense for providing Purge Ports to any other employee group, outside of a smaller allocation of 1.3% for Purge Ports, of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel. This is because a much wider range of personnel are involved in functions necessary to offer, monitor and maintain Purge Ports but the tasks necessary to do so are not a primary or full-time function.

In total, the Exchange allocated 2.2% of its personnel costs to providing Purge

Ports. In turn, the Exchange allocated the remaining 97.8% of its Human Resources expense to membership services, transaction services, connectivity services, other port services and market data. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including Purge Ports, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide Purge Port services to its Market Makers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing Purge Port services, but instead allocated approximately 1.0% of the Exchange's overall depreciation and amortization expense to Purge Ports. The Exchange allocated the remaining depreciation and amortization expense (approximately 99%) toward the cost of providing transaction services, membership services, connectivity services, other port services, and market data.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from Purge Ports, the Exchange will have to be successful in retaining existing Market Makers that wish to maintain Purge Ports or in obtaining new Market Makers that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of connectivity services it will receive additional revenue to offset future cost increases. However, if use of port services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [35]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide port services. Much of the cost relates to monitoring and analysis of data and performance of the network via the subscriber's connection(s). The above cost, namely those associated with hardware, software, and human capital, enable the Exchange to measure network performance with nanosecond granularity. These same costs are also associated with time and money spent seeking to continuously improve the network performance, improving the subscriber's experience, based on monitoring and analysis activity. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for Purge Port services. Subscribers, particularly those of Purge Ports, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services (connections and ports), membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide Purge Port services will equal $822,969. Based on current Purge Port services usage, the Exchange would generate annual revenue of approximately $950,400. The Exchange believes this represents a modest profit of 13.4% when compared to the cost of providing Purge Port services, which could decrease over time.[36]

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing Purge Port services versus the total projected revenue of the Exchange associated with network Purge Port services.

The Proposed Fees are Also Equitable, Reasonable, and Not Unfairly Discriminatory

The Exchange believes that the proposed rule change would promote

[35] For purposes of calculating projected 2024 revenue for Purge Ports, the Exchange used revenues for the most recently completed full month.

[36] Assuming the U.S. inflation rate continues at its current rate, the Exchange believes that the projected profit margins in this proposal will decrease; however, the Exchange cannot predict with any certainty whether the U.S. inflation rate will continue at its current rate or its impact on the Exchange's future profits or losses. *See, e.g., https://www.usinflationcalculator.com/inflation/current-inflation-rates/* (last visited April 15, 2024).

just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market because offering Market Makers optional Purge Port services with a flexible fee structure promotes choice, flexibility, and efficiency. The Exchange believes Purge Ports enhance Market Makers' ability to manage quotes, which would, in turn, improve their risk controls to the benefit of all market participants. The Exchange believes that Purge Ports foster cooperation and coordination with persons engaged in facilitating transactions in securities because designating Purge Ports for purge messages may encourage better use of such ports. This may, concurrent with the ports that carry quotes and other information necessary for market making activities, enable more efficient, as well as fair and reasonable, use of Market Makers' resources. The Exchange believes that proper risk management, including the ability to efficiently cancel multiple quotes quickly when necessary is valuable to all firms, including Market Makers that have heightened quoting obligations that are not applicable to other market participants.

Purge Ports do not relieve Market Makers of their quoting obligations or firm quote obligations under Regulation NMS Rule 602.[37] Specifically, any interest that is executable against a Member's or Market Maker's quotes that is received by the Exchange prior to the time of the removal of quotes request will automatically execute. Market Makers that purge their quotes will not be relieved of the obligation to provide continuous two-sided quotes on a daily basis, nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet their continuous quoting obligation each trading day.[38]

The Exchange also believes that offering Purge Ports at the Matching Engine level promotes risk management across the industry, and thereby facilitates investor protection. Some market participants, in particular the larger firms, could and do build similar risk functionality in their trading systems that permit the flexible cancellation of quotes entered on the Exchange at a high rate. Offering Matching Engine level protections ensures that such functionality is widely available to all firms, including smaller firms that may otherwise not be willing to incur the costs and development work necessary to support their own customized mass cancel functionality.

The Exchange also believes that moving to a per Matching Engine fee for Purge Ports is reasonable due to the Exchange's architecture that provides the Exchange the ability to provide two (2) Purge Ports per Matching Engine.

The Exchange believes that the proposed Purge Port fees are equitable because the proposed Purge Ports are completely voluntary as they relate solely to optional risk management functionality.

The Exchange also believes that the proposed amendments to its Fee Schedule are not unfairly discriminatory because they will apply uniformly to all Market Makers that choose to use the optional Purge Ports. Purge Ports are completely voluntary and, as they relate solely to optional risk management functionality, no Market Maker is required or under any regulatory obligation to utilize them. All Market Makers that voluntarily select this service option will be charged the same amount for the same services. All Market Makers have the option to select any port or connectivity option, and there is no differentiation among Market Makers with regard to the fees charged for the services offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Purge Ports are completely voluntary and are available to all Market Makers on an equal basis at the same cost. While the Exchange believes that Purge Ports provide a valuable service, Market Makers can choose to purchase, or not purchase, these ports based on their own determination of the value and their business needs. No Market Maker is required or under any regulatory obligation to utilize Purge Ports. Accordingly, the Exchange believes that Purge Ports offer appropriate risk management functionality to firms that trade on the Exchange without imposing an unnecessary or inappropriate burden on competition.

The Exchange also does not believe the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to introduce their own purge port functionality and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposal would apply uniformly to any market participant, in that it does not differentiate between Market Makers. The proposal would allow any interested Market Makers to purchase Purge Port functionality based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one comment letter on the Initial Proposal and one comment letter on the Second Proposal, both from the same commenter.[39] These comment letters were submitted not only on these proposals, but also the proposals by the Exchange and its affiliates to amend fees for 10Gb ULL connectivity and certain other ports. The Exchange received one other comment letter on the Second Proposal, another on the Third Proposal, and another on the Fourth Proposal from a separate commenter.[40] Overall, the Exchange believes that the issues raised by the first commenter are not germane to this proposal because they apply primarily to the other fee filings. Also, both commenters raised concerns with the current environment surrounding exchange non-transaction fee proposals that should be addressed by the Commission through rule making, or Congress, more holistically and not through an individual exchange fee filings. However, the commenters do raise one issue that concerns this proposal whereby it asserts that the Exchange's comparison to fees charged by other exchanges for similar ports is irrelevant and unpersuasive. The core of the issue raised is regarding the cost to connect to one exchange compared to the cost to connect to others. A thorough response to this comment would require the Exchange to obtain competitively sensitive information about other exchanges' architecture and how their members connect. The Exchange is not privy to this information. Further, the commenters compare the Exchange's proposed rate to other exchanges that offer purge port functionality across all matching engines for a single fee, but fails to provide the same comparison to other exchanges that charge for purge functionality as proposed herein. Nonetheless, the Exchange notes that it

[37] *See* Exchange Rule 604. *See also generally* Chapter VI of the Exchange's Rules.

[38] *Id.*

[39] *See* letters from Thomas M. Merritt, Deputy General Counsel, Virtu Financial, Inc. (''Virtu''), to Vanessa Countryman, Secretary, Commission, dated November 8, 2023 and January 2, 2024.

[40] *See* letters from John C. Pickford, Counsel, Susquehanna International Group, LLP (''SIG''), to Vanessa Countryman, Secretary, Commission, dated January 4, 2024, March 1, 2024, and April 11, 2024.

is relying on a cost-based justification to support the proposed fee change, not a comparison of the proposed fees to the fees charged by other exchanges for similar purging services. The Exchange does not have insight into the technical architecture of other exchanges so it is difficult to ascertain the number of purge ports a firm would need to connect to another exchange's entire market. Therefore, the Exchange is limited to comparing its proposed fee to other exchanges' purge port fees as listed in their fee schedules.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[41] and Rule 19b–4(f)(2)[42] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–EMERALD–2024–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–EMERALD–2024–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–EMERALD–2024–14 and should be submitted on or before May 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Sherry R. Haywood,

Assistant Secretary.

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[41] 15 U.S.C. 78s(b)(3)(A)(ii).

[42] 17 CFR 240.19b–4(f)(2).

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100037; File No. SR–PEARL–2024–20]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Fee Schedule for Purge Ports

April 26, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 15, 2024, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (the ''Fee Schedule'') to amend fees for MIAX Express Network (''MEO'')[3] Purge Ports (''Purge Ports'').[4]

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings* at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the fees for Purge Ports, which is a function enabling the Exchange's two types of Members,[5] Market Makers[6] and Electronic Exchange Members[7]

[3] ''MEO Interface'' or ''MEO'' means a binary order interface for certain order types as set forth in Rule 516 into the MIAX Pearl System. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[4] The proposed fee change is based on a recent proposal by Nasdaq Phlx LLC (''Phlx'') to adopt fees for purge ports. *See* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[5] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[6] The term ''Market Maker'' or ''MM'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[7] The term ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who

Continued

(''EEMs''), to cancel all open orders or a subset of open orders through a single cancel message. The Exchange currently provides Members the option to purchase Purge Ports to assist in their quoting activity. Purge Ports provide Members with the ability to send purge messages to the Exchange System.[8] Purge Ports are not capable of sending or receiving any other type of messages or information. The use of Purge Ports is completely optional and no rule or regulation requires that a Market Maker utilize them.

The Exchange initially filed the proposal on September 29, 2023 (the ''Initial Proposal'').[9] On November 22, 2023, the Exchange withdrew the Initial Proposal and replaced with a revised filing (the ''Second Proposal'').[10] On January 17, 2024, the Exchange withdrew the Second Proposal and, on January 31, 2024, replaced it with a further revised filing (the ''Third Proposal'').[11] On March 8, 2024, the Exchange withdrew the Third Proposal and replaced it with a further revised filing (the ''Fourth Proposal'').[12] On April 15, 2024, the Exchange withdrew the Fourth Proposal and replaced it with a further revised filing (the ''Fifth Proposal'').

The Exchange is including a cost analysis in this filing to justify the proposed fees. As described more fully below, the cost analysis includes, among other things, descriptions of how the Exchange allocated costs among it and its affiliated exchanges for similar proposed fee changes (separately between MIAX[13] and MIAX Emerald,[14] collectively referred to herein as the ''affiliated markets''), to ensure no cost was allocated more than once, as well as detail supporting its cost allocation processes and explanations as to why a cost allocation in this proposal may differ from the same cost allocation in similar proposals submitted by the affiliated markets. The proposed fees are intended to cover the Exchange's cost of providing Purge Ports with a reasonable mark-up over those costs.

Purge Port Fee Change

Unlike other options exchanges that charge fees for Purge Ports on a per port basis,[15] the Exchange assesses a flat fee of $750 per month, regardless of the number of Purge Ports utilized by a Market Maker. Prior to the Initial Proposal, a Market Maker could request and be allocated two (2) Purge Ports per Matching Engine[16] to which it connects and not all Members connected to all of the Exchange's Matching Engines.

The Exchange now proposes to amend the fee for Purge Ports to align more closely with other exchanges who charge on a per port basis by providing two (2) Purge Ports per Matching Engine for a monthly flat fee of $600 per month per Matching Engine. The only difference with a per port structure is that Members receive two (2) Purge Ports per Matching Engine for the same proposed monthly fee, rather than being charged a separate fee for each Purge Port. The Exchange proposes to charge the proposed fee for Purge Ports per Matching Engine, instead on a per Purge Port basis, due to its System architecture which provides two (2) Purge Ports per Matching Engine for redundancy purposes. In addition, the proposed fee is lower than the comparable fee charged by competing exchanges that also charge on a per port basis, notwithstanding that the Exchange is providing up to two (2) Purge Ports for that same lower fee.[17] Other exchanges may also maintain a different number of matching engines within their architecture than the Exchange (*i.e.,* MIAX maintains twenty-four (24) matching engines, MIAX Pearl Options maintains twelve (12) matching engines, and MIAX Emerald maintains twelve (12) matching engines).

Similar to a per port charge, Members are able to select the Matching Engines that they want to connect to,[18] based on the business needs of each Market Maker, and pay the applicable fee based on the number of Matching Engines and ports utilized. The Exchange believes that the proposed fee provides Members with flexibility to control their Purge Port costs based on the number of Matching Engines each Marker Maker elects to connect to based on each Market Maker's business needs.

* * * * *

A logical port represents a port established by the Exchange within the Exchange's System for trading and billing purposes. Each logical port grants a Member the ability to accomplish a specific function, such as order entry, order cancellation, access to execution reports, and other administrative information.

Purge Ports are designed to assist Members[19] in the management of, and risk control over, their orders, particularly if the firm is dealing with a large number of securities. For example, if a Market Maker detects market indications that may influence the execution potential of their orders, the Market Maker may use Purge Ports to reduce uncertainty and to manage risk by purging all orders in a number of securities. This allows Members to seamlessly avoid unintended executions, while continuing to evaluate the market, their positions, and their risk levels. Purge Ports are used by Members that conduct business activity that exposes them to a large amount of risk across a number of securities. Purge Ports enable Members to cancel all open orders, or a subset of open orders through a single cancel message. The Exchange notes that Purge Ports increase efficiency of already existing functionality enabling the cancellation of orders.

The Exchange operates highly performant systems with significant

is a Member representing as agent Public Customer Orders or Non-Customer Orders on the Exchange and those non-Market Maker Members conducting proprietary trading. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* the Definitions Section of the Fee Schedule and Exchange Rule 100.

[8] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[9] *See* Securities Exchange Act Release No. 98733 (October 12, 2023), 88 FR 71907 (October 18, 2023) (SR–PEARL–2023–52).

[10] *See* Securities Exchange Act Release No. 99090 (December 5, 2023), 88 FR 86193 (December 12, 2023) (SR–PEARL–2023–65).

[11] *See* Securities Exchange Act Release No. 99527 (February 13, 2024), 89 FR 1282 (February 20, 2024) (SR–PEARL–2024–07).

[12] *See* Securities Exchange Act Release No. 99814 (March 20, 2024), 89 FR 21131 (March 26, 2024) (SR–PEARL–2024–13).

[13] The term ''MIAX'' means Miami International Securities Exchange, LLC. *See* Exchange Rule 100.

[14] The term ''MIAX Emerald'' means MIAX Emerald, LLC. *See* Exchange Rule 100.

[15] *See* Cboe BXZ Exchange, Inc. (''BZX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe EDGX Exchange, Inc. (''EDGX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe Exchange, Inc. (''Cboe'') Fee Schedule ($850 per purge port per month). *See also* Nasdaq GEMX, Options 7, Pricing Schedule, Section 6.C.(3). Nasdaq GEMX, LLC (''Nasdaq GEMX'') assesses its members $1,250 per SQF Purge Port per month, subject to a monthly cap of $17,500 for SQF Purge Ports and SQF Ports, applicable to market makers. *See also* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[16] A Matching Engine is a part of the Exchange's electronic system that processes options quotes and trades on a symbol-by-symbol basis. Some matching engines will process option classes with multiple root symbols, and other matching engines will be dedicated to one single option root symbol (for example, options on SPY will be processed by one single matching engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated matching engine. A particular root symbol may not be assigned to multiple matching engines. *See* the Definitions Section of the Fee Schedule.

[17] *See supra* note 15.

[18] The Exchange notes that each Matching Engine corresponds to a specified group of symbols. Certain Market Makers choose to only quote in certain symbols while other Market Makers choose to quote the entire market.

[19] Members seeking to become registered as a Market Maker must comply with the applicable requirements of Chapter VI of the Exchange's Rules.

throughput and determinism which allows participants to enter, update and cancel orders at high rates. Members may currently cancel individual orders through the existing functionality, such as through the use of a mass cancel message by which a Market Maker may request that the Exchange remove all or a subset of its quotations and block all or a subset of its new inbound quotations.[20] Other than Purge Ports being a dedicated line for cancelling quotations, Purge Ports operate in the same manner as a mass cancel message being sent over a different type of port. For example, like Purge Ports, mass cancellations sent over a logical port may be done at either the firm or MPID level. As a result, Members can currently cancel orders in rapid succession across their existing logical ports [21] or through a single cancel message, all open orders or a subset of open orders.

Similarly, Members may also use cancel-on-disconnect control when they experience a disruption in connection to the Exchange to automatically cancel all orders, as configured or instructed by the Member or Market Maker.[22] In addition, the Exchange already provides similar ability to mass cancel orders through the Exchange's risk controls, which are offered at no charge and enables Members to establish pre-determined levels of risk exposure, and can be used to cancel all open orders.[23] Accordingly, the Exchange believes that the Purge Ports provide an efficient option as an alternative to already available services and enhance the Member's ability to manage their risk.

The Exchange believes that market participants benefit from a dedicated purge mechanism for specific Members and to the market as a whole. Members will have the benefit of efficient risk management and purge tools. The market will benefit from potential increased quoting and liquidity as Members may use Purge Ports to manage their risk more robustly. Only Members that request Purge Ports would be subject to the proposed fees, and other Members can continue to operate in exactly the same manner as they do today without dedicated Purge Ports, but with the additional purging capabilities described above.

Implementation Date

The proposed fee change is immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Section 6(b)(5) of the Act,[25] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed fee is consistent with Section 6(b)(4) of the Act [26] because it represents an equitable allocation of reasonable dues, fees and other charges among market participants.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

In proposing to charge fees for port services, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[27] and Rule 19b–4 thereunder,[28] with respect to the types of information exchanges should provide when filing fee changes, and Section 6(b) of the Act,[29] which requires, among other things, that exchange fees be reasonable and equitably allocated,[30] not designed to permit unfair discrimination,[31] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[32] The Exchange reiterates that the legacy exchanges with whom the Exchange vigorously competes for order flow and market share, were not subject to any such diligence or transparency in setting their baseline non-transaction fees, most of which were put in place before the Staff Guidance.[33]

As detailed below, the Exchange recently calculated its aggregate annual costs for providing Purge Ports to be $1,017,523 (or approximately $84,793 per month, rounded to the nearest dollar when dividing the annual cost by 12 months). In order to cover the aggregate costs of providing Purge Ports to its Market Makers going forward and to make a modest profit, as described below, the Exchange proposes to modify its Fee Schedule to charge a fee of $300 per Matching Engine for Purge Ports.

In 2019, the Exchange completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis'').[34] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk and purge functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers''). The Exchange recently update its Cost Analysis using its 2024 estimated budget as described below.

As an initial step, the Exchange determined the total cost for the Exchange and the affiliated markets for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the

[20] *See* Exchange Rule 519C(a) and (b).

[21] Current Exchange port functionality supports cancelation rates that exceed one thousand messages per second and the Exchange's research indicates that certain market participants rely on such functionality and at times utilize such cancelation rates.

[22] *See* Exchange Rule 519C(c).

[23] *See* Exchange Rule 532.

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

[26] 15 U.S.C. 78f(b)(4).

[27] 15 U.S.C. 78s(b)(1).

[28] 17 CFR 240.19b–4.

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(4).

[31] 15 U.S.C. 78f(b)(5).

[32] 15 U.S.C. 78f(b)(8).

[33] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available at https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees* (the ''Staff Guidance'').

[34] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[35] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all costs drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below.

This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below. Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive updated Cost Analysis, which was again recently further refined, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of connectivity and port services, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of Purge Port services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to Purge Port services. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide Purge Port services is $84,793, as further detailed below.

Costs Related to Offering Purge Ports

The following chart details the individual line-item costs considered by the Exchange to be related to offering Purge Ports as well as the percentage of the Exchange's overall costs that such costs represent for each cost driver (*e.g.,* as set forth below, the Exchange allocated approximately 3.5% of its overall Human Resources cost to offering Purge Ports).

[35] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

Cost drivers	Allocated annual cost [a]	Allocated monthly cost [b]	% of all
Human Resources	$776,560	$64,713	3.5
Connectivity (external fees, cabling, switches, etc.)	521	43	0.6
Internet Services and External Market Data	2,949	246	0.6
Data Center	21,359	1,780	1.4
Hardware and Software Maintenance and Licenses	11,069	922	0.6
Depreciation	67,682	5,640	1.7
Allocated Shared Expenses	137,383	11,449	1.5
Total	1,017,523	84,793	2.6

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering Purge Ports. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated markets in their similar proposed fee changes for Purge Ports. This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace. The Exchange provides additional explanation below (including the reason for the deviation) for the significant differences.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining Purge Ports and performance thereof (primarily the Exchange's network infrastructure team, which spends most of their time performing functions necessary to provide port and connectivity services). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to port services. From that portion allocated to the Exchange that applied to ports, the Exchange then allocated a weighted average of 5.4% of each employee's time from the above group to Purge Ports.

The Exchange also allocated Human Resources costs to provide Purge Ports to a limited subset of personnel with ancillary functions related to establishing and maintaining such ports (such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing Purge Ports) and then applied a smaller allocation to such employees' time to Purge Ports (2.4%). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to Purge Ports, whether it is a sales person selling port services, finance personnel billing for port services or providing budget analysis, or information security ensuring that such ports are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing Purge Ports, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing Purge Ports: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated 5.4% of each of their employee's time assigned to the Exchange for Purge Ports, as stated above. Employees from these departments perform numerous functions to support Purge Ports, such as the installation, re-location, configuration, and maintenance of Purge Ports and the hardware they access. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting Purge Ports and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support Purge Ports, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the Purge Ports related

Human Resources costs to the extent that they are involved in overseeing tasks related to providing Purge Ports. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, Etc.)

The Connectivity cost driver includes external fees paid to connect to other exchanges and third parties, cabling and switches required to operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete connections to the Exchange and to connect to external markets. The Exchange notes that its connectivity to external markets vendors is required in order to receive market data to run the Exchange's matching engine and basic operations compliant with existing regulations, primarily Regulation NMS.

The Exchange relies on various connectivity providers for connectivity to the entire U.S. options industry, and infrastructure services for critical components of the network that are necessary to provide and maintain its System Networks and access to its System Networks via 10Gb ULL connectivity. Specifically, the Exchange utilizes connectivity providers to connect to other national securities exchanges and the Options Price Reporting Authority (''OPRA''). The Exchange understands that these service providers provide services to most, if not all, of the other U.S. exchanges and other market participants. Connectivity provided by these service providers is critical to the Exchanges daily operations and performance of its System Networks which includes Purge Ports. Without these services providers, the Exchange would not be able to connect to other national securities exchanges, market data providers or OPRA and, therefore, would not be able to operate and support its System Networks, including Purge Ports. In addition, the connectivity is necessary for the Exchange to notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Also, like other types of ports offered by the Exchange, Purge Ports leverage the Exchange's existing 10Gb ULL connectivity, which also relies on connectivity to other national securities exchanges and OPRA. The Exchange does not employ a separate fee to cover its connectivity provider expense and recoups that expense, in part, by charging for Purge Ports.

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. For purposes of Purge Ports, the Exchange also includes a portion of its costs related to external market data. External market data includes fees paid to third parties, including OPRA, to receive and consume market data from other markets. The Exchange includes external market data costs towards Purge Ports because such market data is necessary to offer certain services related to such ports, such as checking for market conditions (*e.g.,* halted securities). External market data is also consumed at the Matching Engine level for, among other things, as validating quotes on entry against the national best bid or offer (''NBBO'').[36] Purge Ports are a component of the Matching Engine, and used by market participants to cancel multiple resting quotes within the Matching Engine. While resting, the Exchange uses external market data to manage those quotes, such as preventing trade-throughs, and those quotes are also reported to OPRA for inclusion in this consolidated data stream. The Exchange also must notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Thus, since market data from other exchanges is consumed by the Matching Engine to validate quotes and check market conditions, the Exchange believes it is reasonable to allocate a small amount of such costs to Purge Ports.

For the reasons set forth above, the Exchange believes it is reasonable to allocate a small amount of such costs to Purge Ports since market data from other exchanges is consumed at the Exchange's Purge Port level to validate purge messages and the necessity to cancel a resting quote via a purge message or via some other means.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide Purge Ports in the third-party data centers where it maintains its equipment as well as related costs for market data to then enter the Exchange's System. The Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties. The Exchange has allocated a percentage of its Data Center cost (1.4%) to Purge Ports because the third-party data centers and the Exchange's physical equipment contained therein are necessary for providing Purge Ports. In other words, for the Exchange to operate in a dedicated physical space with direct connectivity by market participants to its trading platform, the data centers are a critical component to the provision of Purge Ports. If the Exchange did not maintain such a presence, then Purge Ports would be of little value to market participants.

Hardware and Software Maintenance and Licenses

Hardware and Software Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer Purge Ports for each Matching Engine of the Exchange. This hardware includes servers, network switches, cables, optics, protocol data units, and cabinets, to maintain a state-of-the-art technology platform. Without hardware and software licenses, Purge Ports would not be able to be offered to market participants because hardware and software are necessary to operate the Exchange's Matching Engines, which are necessary to enable the purging of quotes. The Exchange also routinely works to improve the performance of the hardware and software used to operate the Exchange's network and System. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to allocate a certain percentage of its hardware and software expense to help offset those costs of providing Purge Port connectivity to its Matching Engines.

Depreciation

The vast majority of the software the Exchange uses to provide Ports has been developed in-house and the cost of such development, which takes place over an extended period of time and includes not just development work, but also quality assurance and testing to ensure the software works as intended, is depreciated over time once the software is activated in the production

[36] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

environment. Hardware used to provide Purge Ports includes equipment used for testing and monitoring of order entry infrastructure and other physical equipment the Exchange purchased and is also depreciated over time.

All hardware and software, which also includes assets used for testing and monitoring of order entry infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. The Exchange allocated 1.9% of all depreciation costs to providing Purge Ports. The Exchange allocated depreciation costs for depreciated software necessary to operate the Exchange because such software is related to the provision of Purge Ports. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost driver was therefore narrowly tailored to depreciation related to Purge Ports.

Allocated Shared Expenses

Finally, a portion of general shared expenses was allocated to overall Purge Port costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide Purge Ports. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange again notes that the cost of paying directors to serve on its Board of Directors is included in the calculation of Allocated Shared Expenses, and thus a portion of such overall cost amounting to less than 3% of the overall cost for directors was allocated to providing Purge Ports.

Approximate Cost for Purge Port per Month

Based on projected 2024 data, the total monthly cost allocated to Purge Ports of $84,793 was divided by the total number of Matching Engines in which Market Makers used Purge Ports for the month of December 2023, which was 142, resulting in an approximate cost of $597 per Matching Engine per month for Purge Port usage (when rounding to the nearest dollar). The Exchange notes that the flat fee of $600 per month per Matching Engine entitles each Market Maker to two Purge Ports per Matching Engine. The majority of Market Makers are connected to all twenty-four of the Exchange's Matching Engines and utilize Purge Ports on each Matching Engine, except one Market Maker, which only utilizes Purge Ports on three Matching Engines.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core services (including Purge Ports) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal. For instance, in calculating the Human Resources expenses to be allocated to Purge Ports based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a higher percentage of the cost of such personnel (19.3%) given their focus on functions necessary to provide Ports. The salaries of those same personnel were allocated only 5.4% to Purge Ports and the remaining 94.6% was allocated to connectivity, other port services, transaction services, membership services and market data. The Exchange did not allocate any other Human Resources expense for providing Purge Ports to any other employee group, outside of a smaller allocation of 2.4% for Purge Ports, of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel. This is because a much wider range of personnel are involved in functions necessary to offer, monitor and maintain Purge Ports but the tasks necessary to do so are not a primary or full-time function.

In total, the Exchange allocated 3.5% of its personnel costs to providing Purge Ports. In turn, the Exchange allocated the remaining 96.5% of its Human Resources expense to membership services, transaction services, connectivity services, other port services and market data. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including Purge Ports, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide Purge Port services to its Market Makers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing Purge Port services, but instead allocated approximately 1.7% of the Exchange's overall depreciation and amortization expense to Purge Ports. The Exchange allocated the remaining depreciation and amortization expense (approximately 98.3%) toward the cost of providing transaction services, membership services, connectivity services, other port services, and market data.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from Purge Ports, the Exchange will have to be successful in retaining existing Market Makers that wish to maintain Purge Ports or in obtaining new Market Makers that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of connectivity services it will receive additional revenue to offset future cost increases. However, if use of port services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current

projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [37]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide port services. Much of the cost relates to monitoring and analysis of data and performance of the network via the subscriber's connection(s). The above cost, namely those associated with hardware, software, and human capital, enable the Exchange to measure network performance with nanosecond granularity. These same costs are also associated with time and money spent seeking to continuously improve the network performance, improving the subscriber's experience, based on monitoring and analysis activity. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for Purge Port services. Subscribers, particularly those of Purge Ports, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services (connections and ports), membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide Purge Port services will equal $1,017,523. Based on current Purge Port services usage, the Exchange would generate annual revenue of approximately $1,029,600. The Exchange believes this represents a modest profit of 1.2% when compared to the cost of providing Purge Port services, which could decrease over time.[38]

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing Purge Port services versus the total projected revenue of the Exchange associated with network Purge Port services.

The Proposed Fees Are Also Equitable, Reasonable, and Not Unfairly Discriminatory

The Exchange believes that the proposed rule change would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market because offering Members optional Purge Port services with a flexible fee structure promotes choice, flexibility, and efficiency. The Exchange believes Purge Ports enhance Members' ability to manage orders, which would, in turn, improve their risk controls to the benefit of all market participants. The Exchange believes that Purge Ports foster cooperation and coordination with persons engaged in facilitating transactions in securities because designating Purge Ports for purge messages may encourage better use of such ports. This may, concurrent with the ports that carry orders and other information necessary for market making activities, enable more efficient, as well as fair and reasonable, use of Members' resources. The Exchange believes that proper risk management, including the ability to efficiently cancel multiple orders quickly when necessary is valuable to all firms, including Members that have heightened quoting obligations that are not applicable to other market participants.

Purge Ports do not relieve Members of their quoting obligations or firm quote obligations under Regulation NMS Rule 602.[39] Specifically, any interest that is executable against a Member's or Market Maker's orders that is received by the Exchange prior to the time of the removal of orders request will automatically execute. Members that purge their orders will not be relieved of the obligation to provide continuous two- sided orders on a daily basis, nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet their continuous quoting obligation each trading day.[40]

The Exchange also believes that offering Purge Ports at the Matching Engine level promotes risk management across the industry, and thereby facilitates investor protection. Some market participants, in particular the larger firms, could and do build similar risk functionality in their trading systems that permit the flexible cancellation of orders entered on the Exchange at a high rate. Offering Matching Engine level protections ensures that such functionality is widely available to all firms, including smaller firms that may otherwise not be willing to incur the costs and development work necessary to support their own customized mass cancel functionality.

The Exchange also believes that moving to a per Matching Engine fee for Purge Ports is reasonable due to the Exchange's architecture that provides the Exchange the ability to provide two (2) Purge Ports per Matching Engine.

The Exchange believes that the proposed Purge Port fees are equitable because the proposed Purge Ports are completely voluntary as they relate solely to optional risk management functionality.

[37] For purposes of calculating projected 2024 revenue for Purge Ports, the Exchange used revenues for the most recently completed full month.

[38] Assuming the U.S. inflation rate continues at its current rate, the Exchange believes that the projected profit margins in this proposal will decrease; however, the Exchange cannot predict with any certainty whether the U.S. inflation rate will continue at its current rate or its impact on the Exchange's future profits or losses. *See, e.g., https://www.usinflationcalculator.com/inflation/current-inflation-rates/* (last visited April 15, 2024).

[39] *See* Exchange Rule 604. *See also generally* Chapter VI of the Exchange's Rules.

[40] *Id.*

The Exchange also believes that the proposed amendments to its Fee Schedule are not unfairly discriminatory because they will apply uniformly to all Members that choose to use the optional Purge Ports. Purge Ports are completely voluntary and, as they relate solely to optional risk management functionality, no Market Maker is required or under any regulatory obligation to utilize them. All Members that voluntarily select this service option will be charged the same amount for the same services. All Members have the option to select any port or connectivity option, and there is no differentiation among Members with regard to the fees charged for the services offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Purge Ports are completely voluntary and are available to all Members on an equal basis at the same cost. While the Exchange believes that Purge Ports provide a valuable service, Members can choose to purchase, or not purchase, these ports based on their own determination of the value and their business needs. No Member is required or under any regulatory obligation to utilize Purge Ports. Accordingly, the Exchange believes that Purge Ports offer appropriate risk management functionality to firms that trade on the Exchange without imposing an unnecessary or inappropriate burden on competition.

The Exchange also does not believe the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to introduce their own purge port functionality and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposal would apply uniformly to any market participant, in that it does not differentiate between Members. The proposal would allow any interested Members to purchase Purge Port functionality based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one comment letter on the Initial Proposal and one comment letter on the Second Proposal, both from the same commenter.[41] These comment letters were submitted not only on these proposals, but also the proposals by the Exchange and its affiliates to amend fees for 10Gb ULL connectivity and certain other ports. The Exchange received one other comment letter on the Second Proposal, another on the Third Proposal, and another on the Fourth Proposal from a separate commenter.[42] Overall, the Exchange believes that the issues raised by the first commenter are not germane to this proposal because they apply primarily to the other fee filings. Also, both commenters raised concerns with the current environment surrounding exchange non-transaction fee proposals that should be addressed by the Commission through rule making, or Congress, more holistically and not through an individual exchange fee filings. However, the commenters do raise one issue that concerns this proposal whereby it asserts that the Exchange's comparison to fees charged by other exchanges for similar ports is irrelevant and unpersuasive. The core of the issue raised is regarding the cost to connect to one exchange compared to the cost to connect to others. A thorough response to this comment would require the Exchange to obtain competitively sensitive information about other exchanges' architecture and how their members connect. The Exchange is not privy to this information. Further, the commenters compare the Exchange's proposed rate to other exchanges that offer purge port functionality across all matching engines for a single fee, but fails to provide the same comparison to other exchanges that charge for purge functionality as proposed herein. Nonetheless, the Exchange notes that it is relying on a cost-based justification to support the proposed fee change, not a comparison of the proposed fees to the fees charged by other exchanges for similar purging services. The Exchange does not have insight into the technical architecture of other exchanges so it is difficult to ascertain the number of purge ports a firm would need to connect to another exchange's entire market. Therefore, the Exchange is limited to comparing its proposed fee to other exchanges' purge port fees as listed in their fee schedules.

[41] *See* letters from Thomas M. Merritt, Deputy General Counsel, Virtu Financial, Inc. (''Virtu''), to Vanessa Countryman, Secretary, Commission, dated November 8, 2023 and January 2, 2024.

[42] *See* letters from John C. Pickford, Counsel, Susquehanna International Group, LLP (''SIG''), to Vanessa Countryman, Secretary, Commission, dated January 4, 2024, March 1, 2024, and April 11, 2024.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[43] and Rule 19b–4(f)(2)[44] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–PEARL–2024–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2024–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

[43] 15 U.S.C. 78s(b)(3)(A)(ii).

[44] 17 CFR 240.19b–4(f)(2).

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–20 and should be submitted on or before May 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09471 Filed 5–1–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100040; File No. SR–CboeBYX–2024–003]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Amend Rule 11.9(c)(6) and Rule 11.13(a)(4)(D) To Permit the Use of BYX Post Only Orders at Prices Below $1.00

April 26, 2024.

I. Introduction

On January 8, 2024, Cboe BYX Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit the use of BYX Post Only Orders at prices below $1.00. The proposed rule change was published for comment in the **Federal Register** on January 29, 2024.[3] On March 8, 2024, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] The Commission did not receive any comments. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change[7]

The Exchange proposes to amend Rule 11.9(c)(6) and Rule 11.13(a)(4)(D) to modify the treatment of BYX Post Only Orders priced below a dollar on the Exchange. BYX Post Only Orders priced at or above $1.00 will only remove liquidity if the value of the execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the BYX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. Currently, all BYX Post Only Orders priced below $1.00 are automatically treated as orders that remove liquidity. Under the proposed rule change, BYX Post Only Orders priced below $1.00 will be treated in the same manner as BYX Post Only Orders priced at or above $1.00 in that BYX Post Only Orders priced below $1.00 will only remove liquidity if the value of the overall execution (taking into account all applicable fees and rebates) make it economically beneficial for the order to remove liquidity.

The Exchange also proposes to amend Rule 11.13(a)(4)(D) to permit Non-Displayed Orders[8] and orders subject to display-price sliding (collectively, ''Resting Orders'') which are not executable at their most aggressive price due to the presence of a contra-side BYX Post Only Order to be executed at one minimum price variation less aggressive than the order's most aggressive price.[9] Currently, Rule 11.13(a)(4)(D) states that, for securities priced above $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at, in the case of an incoming sell order, one-half minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one-half minimum price variation more than the price of the displayed order. The Exchange proposes that for securities priced below $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at, in the case of an incoming sell order, one minimum price variation less than the price of the displayed order, and, in the case of an incoming buy order, at one minimum price variation more than the price of the displayed order.

III. Proceedings To Determine Whether To Approve or Disapprove SR–CboeBYX–2024–003, and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[10] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide additional comment on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[11] the Commission is providing notice of the grounds for disapproval under consideration. As described above, the Exchange proposes to permit the use of BYX Post Only Orders at prices below $1.00. In addition, as described above, for securities priced

[45] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99413 (January 23, 2024), 89 FR 5582 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 99697, 89 FR 18699 (March 14, 2024) (designating April 26, 2024, as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] For a more detailed description of the proposed rule change, including examples, refer to the Notice, *supra* note 3.

[8] *See* Rule 11.9(c)(11). A ''Non-Displayed Order'' is a market or limit order that is not displayed on the Exchange.

[9] *See* Securities Exchange Act Release No. 64753 (June 27, 2011), 76 FR 38714 (July 1, 2011), SR–BYX–2011–009 (''Resting Order Execution Filing''). The Resting Order Execution Filing introduced an order handling change for certain Non-Displayed Orders and orders subject to display-price sliding that are not executable at prices equal to displayed orders on the opposite side of the market (the ''locking price''). The Resting Order Execution Filing permits Resting Orders priced at or above $1.00 to be executed at one-half minimum price variation less aggressive than the locking price (for bids) and one-half minimum price variation more aggressive than the locking price (for offers), under certain circumstances.

[10] 15 U.S.C. 78s(b)(2)(B).

[11] *Id.*

below $1.00, incoming orders that are market orders or limit orders priced more aggressively than a displayed order on the same side of the market, the Exchange will execute the incoming order at one minimum price variation less (more) than the price of the displayed order for sell (buy) orders.[12] In contrast, under the current rule for securities priced above $1.00, the incoming order would execute at one-half minimum price variation less (more) than the price of the displayed order for sell (buy) orders.[13] The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[14] In addition, Sections 6(b)(5) and 6(b)(8) of the Act, respectively, prohibit the rules of an exchange from being designed to permit unfair discrimination between customers, issuers, brokers, or dealers [15] or imposing any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[16]

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.'' [17] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[18] and any failure of a self-regulatory organization to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[19]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change, is consistent with Sections 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[20] any request for an opportunity to make an oral presentation.[21]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by May 23, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by June 6, 2024. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeBYX–2024–003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR-CboeBYX–2024–003. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–003 and should be submitted by May 23, 2024. Rebuttal comments should be submitted by June 6, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

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[12] According to the Exchange, executing an incoming order at the same price as the price as that of a displayed order on the same side of the market would violate the time priority of the displayed order. *See* Notice *supra* note 3, 89 FR at 5585; *see also* Exchange Rules 11.12(a) and 11.13(a)(4).

[13] *See* Exchange Rule 11.13(a)(4)(D).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(8).

[17] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[18] *See id.*

[19] *See id.*

[20] 17 CFR 240.19b–4.

[21] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[22] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100036; File No. SR–MIAX–2024–22]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule for Purge Ports

April 26, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 15, 2024, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule (the ''Fee Schedule'') to amend fees for Purge Ports.[3]

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the fees for Purge Ports, which is a function enabling Market Makers[4] to cancel all open quotes or a subset of open quotes through a single cancel message. The Exchange currently provides Market Makers the option to purchase Purge Ports to assist in their quoting activity. Purge Ports provide Market Makers with the ability to send purge messages to the Exchange System.[5] Purge Ports are not capable of sending or receiving any other type of messages or information. The use of Purge Ports is completely optional and no rule or regulation requires that a Market Maker utilize them.

The Exchange initially filed the proposal on September 29, 2023 (the ''Initial Proposal'').[6] On November 22, 2023, the Exchange withdrew the Initial Proposal and replaced with a revised filing (the ''Second Proposal'').[7] On January 17, 2024, the Exchange withdrew the Second Proposal and, on January 31, 2024, replaced it with a further revised filing (the ''Third Proposal'').[8] On March 8, 2024, the Exchange withdrew the Third Proposal and replaced it with a further revised filing (the ''Fourth Proposal'').[9] On April 15, 2024, the Exchange withdrew the Fourth Proposal and replaced it with a further revised filing (the ''Fifth Proposal'').

The Exchange is including a cost analysis in this filing to justify the proposed fees. As described more fully below, the cost analysis includes, among other things, descriptions of how the Exchange allocated costs among it and its affiliated exchanges for similar proposed fee changes (separately between MIAX Pearl Options[10] and MIAX Emerald,[11] collectively referred to herein as the ''affiliated markets''), to ensure no cost was allocated more than once, as well as detail supporting its cost allocation processes and explanations as to why a cost allocation in this proposal may differ from the same cost allocation in similar proposals submitted by the affiliated markets. The proposed fees are intended to cover the Exchange's cost of providing Purge Ports with a reasonable mark-up over those costs.

Purge Port Fee Change

Unlike other options exchanges that charge fees for Purge Ports on a per port basis,[12] the Exchange assesses a flat fee of $1,500 per month, regardless of the number of Purge Ports utilized by a Market Maker. Prior to the Initial Proposal, a Market Maker could request and be allocated two (2) Purge Ports per Matching Engine[13] to which it connects and not all Market Makers connected to all of the Exchange's Matching Engines.

The Exchange now proposes to amend the fee for Purge Ports to align more closely with other exchanges who charge on a per port basis by providing two (2) Purge Ports per Matching Engine for a monthly flat fee of $300 per month per Matching Engine. The only difference with a per port structure is that Market Makers receive two (2) Purge Ports per Matching Engine for the same proposed monthly fee, rather than being charged a separate fee for each Purge Port. The Exchange proposes to charge the proposed fee for Purge Ports per Matching Engine, instead on a per Purge Port basis, due to its System architecture which provides two (2) Purge Ports per Matching Engine for redundancy purposes. In addition, the proposed fee is lower than the comparable fee charged by competing exchanges that also charge on a per port basis, notwithstanding that the Exchange is providing up to two (2) Purge Ports for that same lower fee.[14] Other exchanges may also maintain a different number of matching engines within their architecture than the Exchange (*i.e.,* MIAX maintains twenty-

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The proposed fee change is based on a recent proposal by Nasdaq Phlx LLC (''Phlx'') to adopt fees for purge ports. *See* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[4] The term ''Market Makers'' refers to Lead Market Makers (''LMMs''), Primary Lead Market Makers (''PLMMs''), and Registered Market Makers (''RMMs'') collectively. *See* Exchange Rule 100.

[5] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[6] *See* Securities Exchange Act Release No. 98732 (October 12, 2023), 88 FR 71913 (October 18, 2023) (SR–MIAX–2023–37).

[7] *See* Securities Exchange Act Release No. 99088 (December 5, 2023), 88 FR 85958 (December 11, 2023) (SR–MIAX–2023–43).

[8] *See* Securities Exchange Act Release No. 99526 (February 13, 2024), 89 FR 12898 (February 20, 2024) (SR–MIAX–2024–07).

[9] *See* Securities Exchange Act Release No. 99813 (March 20, 2024), 89 FR 21140 (March 26, 2024) (SR–MIAX–2024–14).

[10] MIAX Pearl Options is the options market of MIAX PEARL, LLC (''MIAX Pearl''), which also operates an equities trading facility called MIAX Pearl Equities. *See* Exchange Rule 100 and MIAX Pearl Rule 1901.

[11] The term ''MIAX Emerald'' means MIAX Emerald, LLC. *See* Exchange Rule 100.

[12] *See* Cboe BXZ Exchange, Inc. (''BZX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe EDGX Exchange, Inc. (''EDGX'') Options Fee Schedule, Options Logical Port Fees, Purge Ports ($750 per purge port per month); Cboe Exchange, Inc. (''Cboe'') Fee Schedule ($850 per purge port per month). *See also* Nasdaq GEMX, Options 7, Pricing Schedule, Section 6.C.(3). Nasdaq GEMX, LLC (''Nasdaq GEMX'') assesses its members $1,250 per SQF Purge Port per month, subject to a monthly cap of $17,500 for SQF Purge Ports and SQF Ports, applicable to market makers. *See also* Securities Exchange Act Release No. 97825 (June 30, 2023), 88 FR 43405 (July 7, 2023) (SR–Phlx–2023–28).

[13] A Matching Engine is a part of the MIAX electronic system that processes options quotes and trades on a symbol-by-symbol basis. Some matching engines will process option classes with multiple root symbols, and other matching engines will be dedicated to one single option root symbol (for example, options on SPY will be processed by one single matching engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated matching engine. A particular root symbol may not be assigned to multiple matching engines. *See* Fee Schedule, Section 5)d), note 29.

[14] *See supra* note 12.

four (24) matching engines, MIAX Pearl Options maintains twelve (12) matching engines, and MIAX Emerald maintains twelve (12) matching engines).

Similar to a per port charge, Market Makers are able to select the Matching Engines that they want to connect to,[15] based on the business needs of each Market Maker, and pay the applicable fee based on the number of Matching Engines and ports utilized. The Exchange believes that the proposed fee provides Market Makers with flexibility to control their Purge Port costs based on the number of Matching Engines each Marker Maker elects to connect to based on each Market Maker's business needs.

* * * * *

A logical port represents a port established by the Exchange within the Exchange's System for trading and billing purposes. Each logical port grants a Member [16] the ability to accomplish a specific function, such as order entry, order cancellation, access to execution reports, and other administrative information.

Purge Ports are designed to assist Market Makers [17] in the management of, and risk control over, their quotes, particularly if the firm is dealing with a large number of securities. For example, if a Market Maker detects market indications that may influence the execution potential of their quotes, the Market Maker may use Purge Ports to reduce uncertainty and to manage risk by purging all quotes in a number of securities. This allows Market Makers to seamlessly avoid unintended executions, while continuing to evaluate the market, their positions, and their risk levels. Purge Ports are used by Market Makers that conduct business activity that exposes them to a large amount of risk across a number of securities. Purge Ports enable Market Makers to cancel all open quotes, or a subset of open quotes through a single cancel message. The Exchange notes that Purge Ports increase efficiency of already existing functionality enabling the cancellation of quotes.

The Exchange operates highly performant systems with significant throughput and determinism which allows participants to enter, update and cancel quotes at high rates. Market Makers may currently cancel individual quotes through the existing functionality, such as through the use of a mass cancel message by which a Market Maker may request that the Exchange remove all or a subset of its quotations and block all or a subset of its new inbound quotations.[18] Other than Purge Ports being a dedicated line for cancelling quotations, Purge Ports operate in the same manner as a mass cancel message being sent over a different type of port. For example, like Purge Ports, mass cancellations sent over a logical port may be done at either the firm or MPID level. As a result, Market Makers can currently cancel quotes in rapid succession across their existing logical ports [19] or through a single cancel message, all open quotes or a subset of open quotes.

Similarly, Market Makers may also use cancel-on-disconnect control when they experience a disruption in connection to the Exchange to automatically cancel all quotes, as configured or instructed by the Member or Market Maker.[20] In addition, the Exchange already provides similar ability to mass cancel quotes through the Exchange's risk controls, which are offered at no charge and enables Market Makers to establish pre-determined levels of risk exposure, and can be used to cancel all open quotes.[21] Accordingly, the Exchange believes that the Purge Ports provide an efficient option as an alternative to already available services and enhance the Market Maker's ability to manage their risk.

The Exchange believes that market participants benefit from a dedicated purge mechanism for specific Market Makers and to the market as a whole. Market Makers will have the benefit of efficient risk management and purge tools. The market will benefit from potential increased quoting and liquidity as Market Makers may use Purge Ports to manage their risk more robustly. Only Market Makers that request Purge Ports would be subject to the proposed fees, and other Market Makers can continue to operate in exactly the same manner as they do today without dedicated Purge Ports, but with the additional purging capabilities described above.

Implementation Date

The proposed fee change is immediately effective.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed fee is consistent with Section 6(b)(4) of the Act [24] because it represents an equitable allocation of reasonable dues, fees and other charges among market participants.

Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

In proposing to charge fees for port services, the Exchange is especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and in carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[25] and Rule 19b–4 thereunder,[26] with respect to the types of information exchanges should provide when filing fee changes, and Section 6(b) of the Act,[27] which requires, among other things, that exchange fees be reasonable

[15] The Exchange notes that each Matching Engine corresponds to a specified group of symbols. Certain Market Makers choose to only quote in certain symbols while other Market Makers choose to quote the entire market.

[16] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[17] Members seeking to become registered as a Market Maker must comply with the applicable requirements of Chapter VI of the Exchange's Rules.

[18] *See* Exchange Rule 519C(a) and (b).

[19] Current Exchange port functionality supports cancelation rates that exceed one thousand messages per second and the Exchange's research indicates that certain market participants rely on such functionality and at times utilize such cancelation rates.

[20] *See* Exchange Rule 519C(c).

[21] *See* Exchange Rule 532.

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78f(b)(4).

[25] 15 U.S.C. 78s(b)(1).

[26] 17 CFR 240.19b–4.

[27] 15 U.S.C. 78f(b).

and equitably allocated,[28] not designed to permit unfair discrimination,[29] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[30] This rule change proposal addresses those requirements, and the analysis and data in each of the sections that follow are designed to clearly and comprehensively show how they are met. The Exchange notes that the legacy exchanges with whom the Exchange vigorously competes for order flow and market share, were not subject to any such diligence or transparency in setting their baseline non-transaction fees, most of which were put in place before the Staff Guidance.[31]

As detailed below, the Exchange recently calculated its aggregate annual costs for providing Purge Ports to be $910,413 (or approximately $75,868 per month, rounded to the nearest dollar when dividing the annual cost by 12 months). In order to cover the aggregate costs of providing Purge Ports to its Market Makers going forward and to make a modest profit, as described below, the Exchange proposes to modify its Fee Schedule to charge a fee of $300 per Matching Engine for Purge Ports.

In 2019, the Exchange completed a study of its aggregate costs to produce market data and connectivity (the ''Cost Analysis'').[32] The Cost Analysis required a detailed analysis of the Exchange's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services, physical connectivity, and port access (which provide order entry, cancellation and modification functionality, risk and purge functionality, the ability to receive drop copies, and other functionality). The Exchange separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers''). The Exchange recently update its Cost Analysis using its 2024 estimated budget as described below.

As an initial step, the Exchange determined the total cost for the Exchange and the affiliated markets for each cost driver as part of its 2024 budget review process. The 2024 budget review is a company-wide process that occurs over the course of many months, includes meetings among senior management, department heads, and the Finance Team. Each department head is required to send a ''bottom up'' budget to the Finance Team allocating costs at the profit and loss account and vendor levels for the Exchange and its affiliated markets based on a number of factors, including server counts, additional hardware and software utilization, current or anticipated functional or non-functional development projects, capacity needs, end-of-life or end-of-service intervals, number of members, market model (*e.g.,* price time or pro-rata, simple only or simple and complex markets, auction functionality, etc.), which may impact message traffic, individual system architectures that impact platform size,[33] storage needs, dedicated infrastructure versus shared infrastructure allocated per platform based on the resources required to support each platform, number of available connections, and employees allocated time. All of these factors result in different allocation percentages among the Exchange and its affiliated markets, *i.e.,* the different percentages of the overall cost driver allocated to the Exchange and its affiliated markets will cause the dollar amount of the overall cost allocated among the Exchange and its affiliated markets to also differ. Because the Exchange's parent company currently owns and operates four separate and distinct marketplaces, the Exchange must determine the costs associated with each actual market—as opposed to the Exchange's parent company simply concluding that all costs drivers are the same at each individual marketplace and dividing total cost by four (4) (evenly for each marketplace). Rather, the Exchange's parent company determines an accurate cost for each marketplace, which results in different allocations and amounts across exchanges for the same cost drivers, due to the unique factors of each marketplace as described above. This allocation methodology also ensures that no cost would be allocated twice or double-counted between the Exchange and its affiliated markets. The Finance Team then consolidates the budget and sends it to senior management, including the Chief Financial Officer and Chief Executive Officer, for review and approval. Next, the budget is presented to the Board of Directors and the Finance and Audit Committees for each exchange for their approval. The above steps encompass the first step of the cost allocation process.

The next step involves determining what portion of the cost allocated to the Exchange pursuant to the above methodology is to be allocated to each core service, *e.g.,* connectivity and ports, market data, and transaction services. The Exchange and its affiliated markets adopted an allocation methodology with thoughtful and consistently applied principles to guide how much of a particular cost amount allocated to the Exchange should be allocated within the Exchange to each core service. This is the final step in the cost allocation process and is applied to each of the cost drivers set forth below.

This next level of the allocation methodology at the individual exchange level also took into account factors similar to those set forth under the first step of the allocation methodology process described above, to determine the appropriate allocation to connectivity or market data versus allocations for other services. This allocation methodology was developed through an assessment of costs with senior management intimately familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an allocation of each cost driver to each core service, resulting in the cost allocations described below. Each of the below cost allocations is unique to the Exchange and represents a percentage of overall cost that was allocated to the Exchange pursuant to the initial allocation described above.

By allocating segmented costs to each core service, the Exchange was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity and port services, membership fees, regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity;

[28] 15 U.S.C. 78f(b)(4).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(8).

[31] *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019), *available athttps://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees (the ''Staff Guidance'').*

[32] The Exchange frequently updates it Cost Analysis as strategic initiatives change, costs increase or decrease, and market participant needs and trading activity changes. The Exchange's most recent Cost Analysis was conducted ahead of this filing.

[33] For example, MIAX maintains 24 matching engines, MIAX Pearl Options maintains 12 matching engines, MIAX Pearl Equities maintains 24 matching engines, and MIAX Emerald maintains 12 matching engines.

only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and, the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below. While there is no standardized and generally accepted methodology for the allocation of an exchange's costs, the Exchange's methodology is the result of an extensive review and analysis and will be consistently applied going forward for any other potential fee proposals. In the absence of the Commission attempting to specify a methodology for the allocation of exchanges' interdependent costs, the Exchange will continue to be left with its best efforts to attempt to conduct such an allocation in a thoughtful and reasonable manner.

Through the Exchange's extensive updated Cost Analysis, which was again recently further refined, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of connectivity and port services, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of Purge Port services, and thus bears a relationship that is, ''in nature and closeness,'' directly related to Purge Port services. In turn, the Exchange allocated certain costs more to physical connectivity and others to ports, while certain costs were only allocated to such services at a very low percentage or not at all, using consistent allocation methodologies as described above. Based on this analysis, the Exchange estimates that the aggregate monthly cost to provide Purge Port services is $75,868, as further detailed below.

Costs Related to Offering Purge Ports

The following chart details the individual line-item costs considered by the Exchange to be related to offering Purge Ports as well as the percentage of the Exchange's overall costs that such costs represent for each cost driver (*e.g.,* as set forth below, the Exchange allocated approximately 2.2% of its overall Human Resources cost to offering Purge Ports).

Cost drivers	Allocated annual cost [a]	Allocated monthly cost [b]	% of all
Human Resources	$492,357	$41,030	2.2
Connectivity (external fees, cabling, switches, etc.)	1,036	86	1.1
Internet Services and External Market Data	16,081	1,340	2.1
Data Center	31,102	2,592	2.1
Hardware and Software Maintenance and Licenses	42,539	3,545	2.1
Depreciation	82,610	6,884	1.9
Allocated Shared Expenses	244,688	20,391	2.8
Total	910,413	75,868	2.3

[a] The Annual Cost includes figures rounded to the nearest dollar.
[b] The Monthly Cost was determined by dividing the Annual Cost for each line item by twelve (12) months and rounding up or down to the nearest dollar.

Below are additional details regarding each of the line-item costs considered by the Exchange to be related to offering Purge Ports. While some costs were attempted to be allocated as equally as possible among the Exchange and its affiliated markets, the Exchange notes that some of its cost allocation percentages for certain cost drivers differ when compared to the same cost drivers for the Exchange's affiliated markets in their similar proposed fee changes for Purge Ports. This is because the Exchange's cost allocation methodology utilizes the actual projected costs of the Exchange (which are specific to the Exchange and are independent of the costs projected and utilized by the Exchange's affiliated markets) to determine its actual costs, which may vary across the Exchange and its affiliated markets based on factors that are unique to each marketplace. The Exchange provides additional explanation below (including the reason for the deviation) for the significant differences.

Human Resources

The Exchange notes that it and its affiliated markets anticipate that by year-end 2024, there will be 289 employees (excluding employees at non-options/equities exchange subsidiaries of Miami International Holdings, Inc. (''MIH''), the holding company of the Exchange and its affiliated markets), and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. Specifically, twice a year, and as needed with additional new hires and new project initiatives, in consultation with employees as needed, managers and department heads assign a percentage of time to every employee and then allocate that time amongst the Exchange and its affiliated markets to determine each market's individual Human Resources expense. Then, managers and department heads assign a percentage of each employee's time allocated to the Exchange into buckets including network connectivity, ports, market data, and other exchange services. This process ensures that every employee is 100% allocated, ensuring there is no double counting between the Exchange and its affiliated markets.

For personnel costs (Human Resources), the Exchange calculated an allocation of employee time for employees whose functions include providing and maintaining Purge Ports and performance thereof (primarily the Exchange's network infrastructure team, which spends most of their time performing functions necessary to provide port and connectivity services). As described more fully above, the Exchange's parent company allocates costs to the Exchange and its affiliated markets and then a portion of the Human Resources costs allocated to the Exchange is then allocated to port services. From that portion allocated to the Exchange that applied to ports, the Exchange then allocated a weighted average of 2.7% of each employee's time from the above group to Purge Ports.

The Exchange also allocated Human Resources costs to provide Purge Ports to a limited subset of personnel with ancillary functions related to establishing and maintaining such ports

(such as information security, sales, membership, and finance personnel). The Exchange allocated cost on an employee-by-employee basis (*i.e.,* only including those personnel who support functions related to providing Purge Ports) and then applied a smaller allocation to such employees' time to Purge Ports (1.2%). This other group of personnel with a smaller allocation of Human Resources costs also have a direct nexus to Purge Ports, whether it is a sales person selling port services, finance personnel billing for port services or providing budget analysis, or information security ensuring that such ports are secure and adequately defended from an outside intrusion.

The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing Purge Ports, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of time such employees devote to those tasks. This includes personnel from the Exchange departments that are predominately involved in providing Purge Ports: Business Systems Development, Trading Systems Development, Systems Operations and Network Monitoring, Network and Data Center Operations, Listings, Trading Operations, and Project Management. Again, the Exchange allocated 2.7% of each of their employee's time assigned to the Exchange for Purge Ports, as stated above. Employees from these departments perform numerous functions to support Purge Ports, such as the installation, re-location, configuration, and maintenance of Purge Ports and the hardware they access. This hardware includes servers, routers, switches, firewalls, and monitoring devices. These employees also perform software upgrades, vulnerability assessments, remediation and patch installs, equipment configuration and hardening, as well as performance and capacity management. These employees also engage in research and development analysis for equipment and software supporting Purge Ports and design, and support the development and on-going maintenance of internally-developed applications as well as data capture and analysis, and Member and internal Exchange reports related to network and system performance. The above list of employee functions is not exhaustive of all the functions performed by Exchange employees to support Purge Ports, but illustrates the breath of functions those employees perform in support of the above cost and time allocations.

Lastly, the Exchange notes that senior level executives' time was only allocated to the Purge Ports related Human Resources costs to the extent that they are involved in overseeing tasks related to providing Purge Ports. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

Connectivity (External Fees, Cabling, Switches, etc.)

The Connectivity cost driver includes external fees paid to connect to other exchanges and third parties, cabling and switches required to operate the Exchange. The Connectivity cost driver is more narrowly focused on technology used to complete connections to the Exchange and to connect to external markets. The Exchange notes that its connectivity to external markets vendors is required in order to receive market data to run the Exchange's matching engine and basic operations compliant with existing regulations, primarily Regulation NMS.

The Exchange relies on various connectivity providers for connectivity to the entire U.S. options industry, and infrastructure services for critical components of the network that are necessary to provide and maintain its System Networks and access to its System Networks via 10Gb ULL connectivity. Specifically, the Exchange utilizes connectivity providers to connect to other national securities exchanges and the Options Price Reporting Authority (''OPRA''). The Exchange understands that these service providers provide services to most, if not all, of the other U.S. exchanges and other market participants. Connectivity provided by these service providers is critical to the Exchanges daily operations and performance of its System Networks which includes Purge Ports. Without these services providers, the Exchange would not be able to connect to other national securities exchanges, market data providers or OPRA and, therefore, would not be able to operate and support its System Networks, including Purge Ports. In addition, the connectivity is necessary for the Exchange to notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Also, like other types of ports offered by the Exchange, Purge Ports leverage the Exchange's existing 10Gb ULL connectivity, which also relies on connectivity to other national securities exchanges and OPRA. The Exchange does not employ a separate fee to cover its connectivity provider expense and recoups that expense, in part, by charging for Purge Ports.

Internet Services and External Market Data

The next cost driver consists of internet services and external market data. Internet services includes third-party service providers that provide the internet, fiber and bandwidth connections between the Exchange's networks, primary and secondary data centers, and office locations in Princeton and Miami. For purposes of Purge Ports, the Exchange also includes a portion of its costs related to external market data. External market data includes fees paid to third parties, including OPRA, to receive and consume market data from other markets. The Exchange includes external market data costs towards Purge Ports because such market data is necessary to offer certain services related to such ports, such as checking for market conditions (*e.g.,* halted securities). External market data is also consumed at the Matching Engine level for, among other things, as validating quotes on entry against the national best bid or offer (''NBBO'').[34] Purge Ports are a component of the Matching Engine, and used by market participants to cancel multiple resting quotes within the Matching Engine. While resting, the Exchange uses external market data to manage those quotes, such as preventing trade-throughs, and those quotes are also reported to OPRA for inclusion in this consolidated data stream. The Exchange also must notify OPRA and other market participants that an order has been cancelled, and that quotes may have been cancelled as a result of a Member purging quotes via their Purge Port. Thus, since market data from other exchanges is consumed by the Matching Engine to validate quotes and check market conditions, the Exchange believes it is reasonable to allocate a small amount of such costs to Purge Ports.

For the reasons set forth above, the Exchange believes it is reasonable to allocate a small amount of such costs to Purge Ports since market data from other exchanges is consumed at the Exchange's Purge Port level to validate purge messages and the necessity to

[34] The term ''NBBO'' means the national best bid or offer as calculated by the Exchange based on market information received by the Exchange from OPRA. *See* Exchange Rule 100.

cancel a resting quote via a purge message or via some other means.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide Purge Ports in the third-party data centers where it maintains its equipment as well as related costs for market data to then enter the Exchange's System. The Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third-parties. The Exchange has allocated a percentage of its Data Center cost (2.1%) to Purge Ports because the third-party data centers and the Exchange's physical equipment contained therein are necessary for providing Purge Ports. In other words, for the Exchange to operate in a dedicated physical space with direct connectivity by market participants to its trading platform, the data centers are a critical component to the provision of Purge Ports. If the Exchange did not maintain such a presence, then Purge Ports would be of little value to market participants.

Hardware and Software Maintenance and Licenses

Hardware and Software Licenses includes hardware and software licenses used to operate and monitor physical assets necessary to offer Purge Ports for each Matching Engine of the Exchange. This hardware includes servers, network switches, cables, optics, protocol data units, and cabinets, to maintain a state-of-the-art technology platform. Without hardware and software licenses, Purge Ports would not be able to be offered to market participants because hardware and software are necessary to operate the Exchange's Matching Engines, which are necessary to enable the purging of quotes. The Exchange also routinely works to improve the performance of the hardware and software used to operate the Exchange's network and System. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to allocate a certain percentage of its hardware and software expense to help offset those costs of providing Purge Port connectivity to its Matching Engines.

Depreciation

The vast majority of the software the Exchange uses to provide Ports has been developed in-house and the cost of such development, which takes place over an extended period of time and includes not just development work, but also quality assurance and testing to ensure the software works as intended, is depreciated over time once the software is activated in the production environment. Hardware used to provide Purge Ports includes equipment used for testing and monitoring of order entry infrastructure and other physical equipment the Exchange purchased and is also depreciated over time.

All hardware and software, which also includes assets used for testing and monitoring of order entry infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. The Exchange allocated 1.9% of all depreciation costs to providing Purge Ports. The Exchange allocated depreciation costs for depreciated software necessary to operate the Exchange because such software is related to the provision of Purge Ports. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost driver was therefore narrowly tailored to depreciation related to Purge Ports.

Allocated Shared Expenses

Finally, a portion of general shared expenses was allocated to overall Purge Port costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide Purge Ports. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange again notes that the cost of paying directors to serve on its Board of Directors is included in the calculation of Allocated Shared Expenses, and thus a portion of such overall cost amounting to less than 3% of the overall cost for directors was allocated to providing Purge Ports.

Approximate Cost for Purge Ports per Month

Based on projected 2024 data, the total monthly cost allocated to Purge Ports of $75,868 was divided by the total number of Matching Engines in which Market Makers used Purge Ports for the month of December 2023, which was 291, resulting in an approximate cost of $261 per Matching Engine per month for Purge Port usage (when rounding to the nearest dollar). The Exchange notes that the flat fee of $300 per month per Matching Engine entitles each Market Maker to two Purge Ports per Matching Engine. The majority of Market Makers are connected to all twenty-four of the Exchange's Matching Engines and utilize Purge Ports on each Matching Engine, except one Market Maker, which only utilizes Purge Ports on three Matching Engines.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core services (including Purge Ports) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal. For instance, in calculating the Human Resources expenses to be allocated to Purge Ports based upon the above described methodology, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a higher percentage of the cost of such personnel (19.6%) given their focus on functions necessary to provide Ports. The salaries of those same personnel were allocated only 2.7 to Purge Ports and the remaining 97.3% was allocated to connectivity, other port services, transaction services, membership services and market data. The Exchange did not allocate any other Human Resources expense for providing Purge Ports to any other employee group, outside of a smaller allocation of 1.2% for Purge Ports, of the cost associated with certain specified personnel who work closely with and support network infrastructure personnel. This is because a much wider range of personnel are involved in functions necessary to offer, monitor and maintain Purge Ports but the tasks necessary to do so are not a primary or full-time function.

In total, the Exchange allocated 2.2% of its personnel costs to providing Purge Ports. In turn, the Exchange allocated the remaining 97.8% of its Human Resources expense to membership services, transaction services, connectivity services, other port services and market data. Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not

double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including Purge Ports, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide Purge Port services to its Market Makers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing Purge Port services, but instead allocated approximately 1.9% of the Exchange's overall depreciation and amortization expense to Purge Ports. The Exchange allocated the remaining depreciation and amortization expense (approximately 98.1%) toward the cost of providing transaction services, membership services, connectivity services, other port services, and market data.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. The Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from Purge Ports, the Exchange will have to be successful in retaining existing Market Makers that wish to maintain Purge Ports or in obtaining new Market Makers that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis is based on the Exchange's 2024 fiscal year of operations and projections. It is possible, however, that actual costs may be higher or lower. To the extent the Exchange sees growth in use of connectivity services it will receive additional revenue to offset future cost increases. However, if use of port services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange may propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Projected Revenue [35]

The proposed fees will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide port services. Much of the cost relates to monitoring and analysis of data and performance of the network via the subscriber's connection(s). The above cost, namely those associated with hardware, software, and human capital, enable the Exchange to measure network performance with nanosecond granularity. These same costs are also associated with time and money spent seeking to continuously improve the network performance, improving the subscriber's experience, based on monitoring and analysis activity. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by amending fees for Purge Port services. Subscribers, particularly those of Purge Ports, expect the Exchange to provide this level of support so they continue to receive the performance they expect. This differentiates the Exchange from its competitors. As detailed above, the Exchange has five primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services (connections and ports), membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these five primary sources of revenue.

The Exchange's Cost Analysis estimates the annual cost to provide Purge Port services will equal $910,413. Based on current Purge Port services usage, the Exchange would generate annual revenue of approximately $1,047,600. The Exchange believes this represents a modest profit of 13.1% when compared to the cost of providing Purge Port services, which could decrease over time.[36]

Based on the above discussion, the Exchange believes that even if the Exchange earns the above revenue or incrementally more or less, the proposed fees are fair and reasonable because they will not result in pricing that deviates from that of other exchanges or a supra-competitive profit, when comparing the total expense of the Exchange associated with providing Purge Port services versus the total projected revenue of the Exchange associated with network Purge Port services.

The Proposed Fees Are Also Equitable, Reasonable, and Not Unfairly Discriminatory

The Exchange believes that the proposed rule change would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market because offering Market Makers optional Purge Port services with a flexible fee structure promotes choice, flexibility, and efficiency. The Exchange believes Purge Ports enhance Market Makers' ability to manage quotes, which

[35] For purposes of calculating projected 2024 revenue for Purge Ports, the Exchange used revenues for the most recently completed full month.

[36] Assuming the U.S. inflation rate continues at its current rate, the Exchange believes that the projected profit margins in this proposal will decrease; however, the Exchange cannot predict with any certainty whether the U.S. inflation rate will continue at its current rate or its impact on the Exchange's future profits or losses. *See, e.g., https://www.usinflationcalculator.com/inflation/current-inflation-rates/* (last visited April 15, 2024).

would, in turn, improve their risk controls to the benefit of all market participants. The Exchange believes that Purge Ports foster cooperation and coordination with persons engaged in facilitating transactions in securities because designating Purge Ports for purge messages may encourage better use of such ports. This may, concurrent with the ports that carry quotes and other information necessary for market making activities, enable more efficient, as well as fair and reasonable, use of Market Makers' resources. The Exchange believes that proper risk management, including the ability to efficiently cancel multiple quotes quickly when necessary is valuable to all firms, including Market Makers that have heightened quoting obligations that are not applicable to other market participants.

Purge Ports do not relieve Market Makers of their quoting obligations or firm quote obligations under Regulation NMS Rule 602.[37] Specifically, any interest that is executable against a Member's or Market Maker's quotes that is received by the Exchange prior to the time of the removal of quotes request will automatically execute. Market Makers that purge their quotes will not be relieved of the obligation to provide continuous two-sided quotes on a daily basis, nor will it prohibit the Exchange from taking disciplinary action against a Market Maker for failing to meet their continuous quoting obligation each trading day.[38]

The Exchange also believes that offering Purge Ports at the Matching Engine level promotes risk management across the industry, and thereby facilitates investor protection. Some market participants, in particular the larger firms, could and do build similar risk functionality in their trading systems that permit the flexible cancellation of quotes entered on the Exchange at a high rate. Offering Matching Engine level protections ensures that such functionality is widely available to all firms, including smaller firms that may otherwise not be willing to incur the costs and development work necessary to support their own customized mass cancel functionality. The Exchange also believes that moving to a per Matching Engine fee for Purge Ports is reasonable due to the Exchange's architecture that provides the Exchange the ability to provide two (2) Purge Ports per Matching Engine.

The Exchange believes that the proposed Purge Port fees are equitable because the proposed Purge Ports are completely voluntary as they relate solely to optional risk management functionality.

The Exchange also believes that the proposed amendments to its Fee Schedule are not unfairly discriminatory because they will apply uniformly to all Market Makers that choose to use the optional Purge Ports. Purge Ports are completely voluntary and, as they relate solely to optional risk management functionality, no Market Maker is required or under any regulatory obligation to utilize them. All Market Makers that voluntarily select this service option will be charged the same amount for the same services. All Market Makers have the option to select any port or connectivity option, and there is no differentiation among Market Makers with regard to the fees charged for the services offered by the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Purge Ports are completely voluntary and are available to all Market Makers on an equal basis at the same cost. While the Exchange believes that Purge Ports provide a valuable service, Market Makers can choose to purchase, or not purchase, these ports based on their own determination of the value and their business needs. No Market Maker is required or under any regulatory obligation to utilize Purge Ports. Accordingly, the Exchange believes that Purge Ports offer appropriate risk management functionality to firms that trade on the Exchange without imposing an unnecessary or inappropriate burden on competition.

The Exchange also does not believe the proposal would cause any unnecessary or inappropriate burden on intermarket competition as other exchanges are free to introduce their own purge port functionality and lower their prices to better compete with the Exchange's offering. The Exchange does not believe the proposed rule change would cause any unnecessary or inappropriate burden on intramarket competition. Particularly, the proposal would apply uniformly to any market participant, in that it does not differentiate between Market Makers. The proposal would allow any interested Market Makers to purchase Purge Port functionality based on their business needs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange received one comment letter on the Initial Proposal and one comment letter on the Second Proposal, both from the same commenter.[39] These comment letters were submitted not only on these proposals, but also the proposals by the Exchange and its affiliates to amend fees for 10Gb ULL connectivity and certain other ports. The Exchange received one other comment letter on the Second Proposal, another on the Third Proposal, and another on the Fourth Proposal from a separate commenter.[40] Overall, the Exchange believes that the issues raised by the first commenter are not germane to this proposal because they apply primarily to the other fee filings. Also, both commenters raised concerns with the current environment surrounding exchange non-transaction fee proposals that should be addressed by the Commission through rule making, or Congress, more holistically and not through an individual exchange fee filings. However, the commenters do raise one issue that concerns this proposal whereby it asserts that the Exchange's comparison to fees charged by other exchanges for similar ports is irrelevant and unpersuasive. The core of the issue raised is regarding the cost to connect to one exchange compared to the cost to connect to others. A thorough response to this comment would require the Exchange to obtain competitively sensitive information about other exchanges' architecture and how their members connect. The Exchange is not privy to this information. Further, the commenters compare the Exchange's proposed rate to other exchanges that offer purge port functionality across all matching engines for a single fee, but fails to provide the same comparison to other exchanges that charge for purge functionality as proposed herein. Nonetheless, the Exchange notes that it is relying on a cost-based justification to support the proposed fee change, not a comparison of the proposed fees to the fees charged by other exchanges for similar purging services. The Exchange does not have insight into the technical architecture of other exchanges so it is difficult to ascertain the number of purge ports a firm would need to

[37] *See* Exchange Rule 604. *See also generally* Chapter VI of the Exchange's Rules.

[38] *Id.*

[39] *See* letters from Thomas M. Merritt, Deputy General Counsel, Virtu Financial, Inc. (''Virtu''), to Vanessa Countryman, Secretary, Commission, dated November 8, 2023 and January 2, 2024.

[40] *See* letters from John C. Pickford, Counsel, Susquehanna International Group, LLP (''SIG''), to Vanessa Countryman, Secretary, Commission, dated January 4, 2024, March 1, 2024, and April 11, 2024.

connect to another exchange's entire market. Therefore, the Exchange is limited to comparing its proposed fee to other exchanges' purge port fees as listed in their fee schedules.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[41] and Rule 19b–4(f)(2)[42] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2024–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2024–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2024–22 and should be submitted on or before May 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09470 Filed 5–1–24; 8:45 am]

BILLING CODE 8011–01–P

[41] 15 U.S.C. 78s(b)(3)(A)(ii).

[42] 17 CFR 240.19b–4(f)(2).

[43] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20274 and #20275; Alaska Disaster Number AK–20003]

Administrative Disaster Declaration of a Rural Area for the State of Alaska

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative disaster declaration of a rural area for the State of ALASKA dated 04/26/2024.

Incident: Severe Storm, Flooding, and Landslides.

Incident Period: 11/20/2023.

DATES: Issued on 04/26/2024.

Physical Loan Application Deadline Date: 06/25/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 01/27/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration of a rural area, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Southeast Island REAA

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 202749 and for economic injury is 202750.

The State which received an EIDL Declaration is Alaska.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2024–09517 Filed 5–1–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an

additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before June 3, 2024.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: The information collected from the public, including our program participants and stakeholders, will help ensure users have an effective, and satisfying experience with the programs and activities offered or sponsored by the Small Business Administration. The information will provide insights into the public's perceptions, experience, and expectations, and help focus attention on areas where communication, training or changes in operations might improve delivery of products or services.

Solicitation of Public Comments: Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

OMB Control: 3245–0398.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Description of Respondents: Program participants and stakeholders, SBA Form Number: N/A.

Estimated Annual Responses: 500,000.

Estimated Annual Hour Burden: 70,000.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2024–09519 Filed 5–1–24; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1305 (Sub No. 1)]

Great Redwood Trail Agency—Adverse Abandonment—Mendocino Railway in Mendocino County, Cal.

On April 12, 2024, Great Redwood Trail Agency (GRTA), a public agency created by the State of California, filed an application under 49 U.S.C. 10903 requesting that the Surface Transportation Board (Board) authorize the third-party, or ''adverse,'' abandonment of an approximately 40-mile rail line owned by Mendocino Railway (MR) that extends between milepost 0 at Fort Bragg and milepost 40 at Willits, in Mendocino County, Cal. (the Line). The Line traverses U.S. Postal Service Zip Codes 95437 and 95490.

According to GRTA, the Line has not been used for Board-regulated rail transportation for over 20 years. GRTA states no rail shipments have originated or terminated on the Line since it was purchased out of bankruptcy by MR in 2004, *see Mendocino Ry.—Acquis. Exemption—Assets of the Cal. W. R.R.,* FD 34465 (STB served Apr. 9, 2004), and that the last business to use the Line ceased operations in 2002. GRTA also states MR has no reasonable prospects for future business along the Line as there is no need for rail service in this area, and that the Line is no longer connected to the interstate freight rail system.

GRTA explains that it is seeking adverse abandonment to support the transformation of a connecting 307-mile rail line (the GRTA Line) into a trail. According to the application, under California law, GRTA must seek abandonment of the GRTA Line and seek railbanking thereon. Without the abandonment of the Line, GRTA states it would be prohibited from seeking abandonment of a portion of the GRTA Line because such action would leave the Line stranded from the interstate rail network.

In a decision served in this proceeding on August 21, 2023, GRTA was granted exemptions from several statutory provisions as well as waivers of certain Board regulations that the Board concluded were inapplicable and unneeded in connection with GRTA's anticipated application.

According to GRTA, the Line does not contain any federally granted rights-of way. GRTA states that any documentation in its possession will be made available promptly to those requesting it. GRTA's entire case-in-chief for adverse abandonment was filed with the application.

The interests of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

Any interested person may file comments concerning the proposed adverse abandonment or protests (including protestant's entire opposition case) by May 28, 2024. Persons who may oppose the proposed adverse abandonment but who do not wish to participate fully in the process by submitting verified statements of witnesses containing detailed evidence should file comments. Persons opposing the proposed adverse abandonment who wish to participate actively and fully in the process should file a protest, observing the filing, service, and content requirements of 49 CFR 1152.25. GRTA's reply is due by June 11, 2024.

Any request for an interim trail use/railbanking condition under 16 U.S.C. 1247(d) and 49 CFR 1152.29 must be filed by May 28, 2024,[1] and should address whether the issuance of a certificate of interim trail use or abandonment in this case would be consistent with the grant of an adverse abandonment application.

All pleadings, referring to Docket No. AB 1305 (Sub-No. 1), should be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on GRTA's representative, Daniel Elliott, GKG Law, P.C., 1055 Thomas Jefferson Street NW, Suite 620, Washington, DC 20007. Except as otherwise set forth in 49 CFR part 1152, every document filed with the Board must be served on all parties to this adverse abandonment proceeding. *See* 49 CFR 1104.12(a).

A Draft Environmental Assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by the Board's Office of Environmental Analysis (OEA) will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Any other persons who would like to obtain a copy of the Draft EA (or EIS) may contact OEA by phone at the number listed below. Draft EAs normally will be made available within 33 days of the filing of the application, and the deadline for submission of comments on the Draft EA will generally be within 30 days of its service. The comments received will

[1] Filing fees for interim trail use/railbanking requests can be found at 49 CFR 1002.2(f)(27).

be addressed in a Final EA (or EIS) and the Board's decision. A Supplemental Final EA (or EIS) may be issued where appropriate.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to OEA at (202) 245–0305. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245.

Board decisions and notices are available at *www.stb.gov.*

Decided: April 29, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2024–09578 Filed 5–1–24; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36766]

East Ohio Valley Railway LLC—Lease and Operation Exemption Containing Interchange Commitment—Norfolk Southern Railway Company

East Ohio Valley Railway LLC (EOVR), a Class III rail carrier, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to lease from Norfolk Southern Railway (NSR) and operate a line of railroad with two segments: (1) approximately 16.5 miles between RO 44.0 near Bellaire, Ohio, and RO 60.5 near Powhatan Point, Ohio; and (2) 1.78 miles of rail between OP 0.0 and OP 1.78 near Powhatan Point (collectively, the Line).

According to the verified notice, EOVR and NSR have reached an agreement pursuant to which EOVR will lease and operate the Line. EOVR states that the Line does not physically connect to any other carrier and NSR will be the exclusive interchange partner for EOVR.

EOVR certifies that its projected annual revenues from this transaction will not result in its becoming a Class I or Class II rail carrier and will not exceed $5 million. EOVR also certifies that the agreement with NSR contains a provision that, through a per-car penalty, would limit EOVR's ability to interchange with a third-party carrier if that ever became physically possible. EOVR has provided additional information regarding the interchange commitment, as required by 49 CFR 1150.43(h).[1]

The transaction may be consummated on or after May 16, 2024, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 9, 2024.

All pleadings, referring to Docket No. FD 36766, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on EOVR's representative, William A. Mullins, Mullins Law Group, 2401 Pennsylvania Ave. NW, Suite 300, Washington, DC 20037.

According to EOVR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 26, 2024.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2024–09577 Filed 5–1–24; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver With Respect to Land; John Glenn Columbus International Airport, Columbus, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change approximately 2.392 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property located at John Glenn Columbus International Airport, Columbus, OH. The property is located in the northwest portion of the airport along the north side of Johnstown Road, west of the Runway Protection Zone for Runway 10L. The aforementioned land is proposed to be sold for future development of an office/warehouse building and is not needed for aeronautical use.

DATES: Comments must be received on or before June 3, 2024.

ADDRESSES: All requisite and supporting documentation will be made available for review by appointment at the FAA Detroit Airports District Office, Mark Grennell, Program Manager, 11677 S Wayne Rd., Romulus, MI 48174. Telephone: (734) 229–2900/Fax: (734) 229–2950.

Written comments on the Sponsor's request may be submitted using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* and follow the instructions for sending your comments electronically.
- *Mail:* Mark Grennell, Program Manager, Federal Aviation Administration, Detroit Airports District Office, 11677 S Wayne Rd., Romulus, MI 48174–1412.
- *Hand Delivery:* Deliver to mail address above between 8 a.m. and 5 p.m. Monday through Friday, excluding Federal holidays.
- *Fax:* (734) 229–2950.

FOR FURTHER INFORMATION CONTACT: Mark Grennell, Program Manager, Federal Aviation Administration, Detroit Airports District Office, 11677 S Wayne Rd., Romulus, MI 48174. Telephone Number: (734) 229–2900/ Fax: (734) 229–2950.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose.

The subject property is currently undeveloped vacant land. The Columbus Regional Airport Authority (CRAA), sponsor of the John Glenn Columbus International Airport, is proposing to dispose of the property for compatible non-aeronautical development under the Sponsor's obligations of Grant Assurance 31, *Disposal of Land.* The 2.392-acre property, made up of thirteen parcels, was acquired in 1994 for noise compatibility with FAA Airport Improvement Program participation, grant number 3–39–0025–19. The anticipated future development includes a one-story office building and an office/warehouse building. CRAA plans to sell the property at fair market value to a proposed developer who will then develop the two buildings.

[1] EOVR filed a copy of the agreement under seal with the verified notice. *See* 49 CFR 1150.43(h)(1).

The disposition of proceeds from the sale of the airport property will be in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the John Glenn Columbus International Airport, Columbus, OH, from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA.

Legal Description

Parcel I: 190–001636–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 3 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel II: 190–001637–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 4 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel III: 190–001635–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 2 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel IV: 190–001638–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 5 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following 120 Square Foot tract as conveyed by Herbert R. Mengert and Jean R. Menger to The Ohio Fuel and Gas Company by document recorded on October 11, 1926 of record in Deed Book 845 Page 65.

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being a part of Lot Number Five (No. 5) of Herbert R. Mengerts' Maple Lawn Addition to the City of Columbus as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book No. 16, page 51, Recorder's Office, Franklin County, Ohio; said part of said lot number five being a tract of ground ten feet by twelve feet (10 ft. x 12 ft.) in area, facing ten (10) feet upon Sterling Street and twelve (12) feet upon the alley along the Northern and Northwestern border of said lot and then South ten (10) feet and West twelve (12) feet to the place of beginning, containing in all one hundred twenty (120) square feet.

Parcel V: 190–001771–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 138 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel VI: 190–001722–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 139 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following 0.12 Acre tract as conveyed by Jean R. Mengert to The State of Ohio, by document recorded on August 17, 1964 of record in Miscellaneous Book 136 Page 577.

Beginning at the northwest corner of said lot; thence along the north line of said lot 10 feet more or less to a point; thence across said lot to a point which is on the west line of said lot; thence north 9 feet more or less to the point of beginning.

Parcel VII: 190–001773–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 140 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following 0.09 Acre tract as conveyed by Jean R. Mengert to The State of Ohio, by document recorded on August 17, 1964 of record in Miscellaneous Book 136 Page 577.

Beginning at a point which is the northwest corner of said lot; thence along the north line of said lot 67 feet more or less to a point; thence across said lot 140 to a point on the south line of said lot; thence along the said south line 10 feet more or less to a point which is the southeast corner of said lot 140; thence along the west line of said lot 45 feet to the point of beginning.

Parcel VIII: 190–001774–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 141 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following 0.11 Acre tract as conveyed by Jean R. Mengert to The State of Ohio, by document recorded on August 17, 1964 of record in Miscellaneous Book 136 Page 577.

Beginning at a point which is the northwest corner of said lot; thence along the north line of said lot 112 feet to the northeast corner of said lot, being also the west right of way of Floway Drive, 14 feet more or less to a point; thence across said lot to a point on the south line of lot 141; thence along the south line of lot 141, 67 feet more or less to a point which is the southeast corner of said lot; thence along the west line of said lot 50 feet to the point of beginning.

Parcel IX: 190–000402–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 1 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel X: 190–001768–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 135 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following tract as conveyed by Esther M. Willford and Maxwell L. Willford to The State of Ohio, by document recorded on August 7, 1967 of record in Deed Book 2417 Page 221.

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being part of lot 135 of the Maple Lawn Addition as recorded in Plat Book 16, Page 51, Recorders Office, Franklin County, Ohio and more fully described as follows:

Beginning at a point which is the northwest corner of said Lot 135; thence along the north line of said lot, 79 feet more or less to a point; thence across said lot to a point which is on the south line of said lot; thence along the said south line 13 feet more or less; thence along the west line of said lot, being also the east right of way line of Sterling Avenue, 50 feet to the point of beginning.

Parcel XI: 190–001769–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 136 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Less and Excepting therefrom the following tract as conveyed by Esther M. Willford and Maxwell L. Willford to The State of Ohio, by document recorded on August 7, 1967 of record in Deed Book 2417 Page 221.

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being part of lot 136 of the Maple Lawn Addition as recorded in Plat Book 16, Page 51, Recorders Office, Franklin County, Ohio and more fully described as follows:

Beginning at a point which is the northwest corner of said Lot 136; thence east along the north line of said lot 136, 13 feet more or less to a point; thence across said lot to a point on the west line of said lot said point being also 120.00 feet right of centerline Station 1088+41.21 of the above mentioned centerline survey; thence north along said west line being the east right of way line of existing Sterling Avenue, 10 feet more or less to the point of beginning.

Parcel XII: 190–001770–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being Lot Number 137 in Maple Lawn Addition, as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book 16 Page 31, Recorder's Office, Franklin County, Ohio.

Parcel XIII: 190–001939–00

Situated in the State of Ohio, County of Franklin, and in the Township of Mifflin:

Being a part of Lot Number Five (No. 5) of Herbert R. Mengerts' Maple Lawn Addition to the City of Columbus as the same is numbered and delineated upon the recorded plat thereof, of record in Plat Book No. 16, page 51, Recorder's Office, Franklin County, Ohio; said part of said lot number five being a tract of ground ten feet by twelve feet (10 ft. x 12 ft.) in area, facing ten (10) feet upon Sterling Street and twelve (12) feet upon the alley along the Northern and Northwestern border of said lot and then South ten (10) feet and West twelve (12) feet to the place of beginning, containing in all one hundred twenty (120) square feet.

Being the same premises conveyed to The Ohio Fuel Gas Company by Herbert R. Mengert and Jane Rowland Mengert, husband and wife, by deed dated August 19, 1926, and recorded in Deed Book Volume 845, page 65 of the Deed Records of Franklin County, Ohio.

Parcel XIV:

Together with any and all interest contained in the portions of Right of Way as vacated by the Franklin County Commissioners in Road Record 27 Page 144 and Recorded in Instrument 199903260075325. (As to All Parcels)

Issued in Romulus, Michigan, on April 25, 2024.

Stephanie R. Swann,

Deputy Manager, Detroit Airports District Office, FAA, Great Lakes Region.

[FR Doc. 2024–09568 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0031]

Agency Information Collection Activities: Notice of Request for Revision of a Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for revision of a currently approved information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for a renewal of an existing information collection. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by June 3, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0031 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.*

Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Daniel Jenkins, 202–366–1067, *Daniel.jenkins@dot.gov,* National Travel Behavior Data Program Manager, Federal Highway Administration, Office of Policy, 1200 New Jersey Avenue SE, Room E83–414, Washington, DC 20590, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: We published a **Federal Register** Notice with a 60-day public comment period on this information collection on December 14, 2023, at [88 FR 86719]. The comments and FHWA's responses to the 60-day notice are below:

Comment 1

I admire embracing the internet as a survey tool. Too often the decrease in landline usage has been seen as the harbinger of the survey's death. Taking advantage of changing technology, not only the internet but also smartphones, points to intelligent survey design and strategy. Also, the estimated total number of burden hours makes sense and parallels the importance of these survey results in evaluating transit in the United States. I would be curious to learn if the initial offer of 2 dollars is enough to garner the interest of most survey takers, and how much total money is earmarked for compensating survey takers. I agree that 2 dollars is a better incentive than nothing, but I fear the number might not be enticing enough for most survey takers. Of

course, the total compensation for completing the survey is 20 dollars, so perhaps that might be enough incentive even if the initial offering appears minute. I am also curious as to what determines the frequency of these surveys and perhaps the final proposal could briefly explain the history of past surveys and how the USDOT determines when another survey is due. In any case, I think the survey as proposed holds tremendous importance for federal and state agencies, especially in the face of climate change. Climate change is already impacting how Americans move, from the buying of electric cars to the shunning of a walk outside because the heat is too intense, and gaining knowledge about these changing trends could help us embrace a greener future.

DOT Response

Incentives: The amount to offer as an initial incentive was tested as part of the 2022 NHTS pilot. In that test, the initial amount varied between $2 and $5. The difference in participation levels between the two groups was 1.7%, suggesting that the $2 incentive was strong enough to elicit participation from the general public.

Title: 2024 Next Generation National Household Travel Survey (NextGen NHTS).

OMB Control: 2125–0545.

Background: Title 23, United States Code, Section 502 authorizes the USDOT to carry out advanced research and transportation research to measure the performance of the surface transportation systems in the US, including the efficiency, energy use, air quality, congestion, and safety of the highway and intermodal transportation systems. The USDOT is charged with the overall responsibility to obtain current information on national patterns of travel, which establishes a data base to better understand travel behavior, evaluate the use of transportation facilities, and gauge the impact of the USDOT's policies and programs.

The NHTS is the USDOT's authoritative nationally representative data source for daily passenger travel. This inventory of travel behavior reflects travel mode (*e.g.,* private vehicles, public transportation, walk and bike) and trip purpose (*e.g.,* travel to work, school, recreation, personal/family trips) by U.S. household residents. Survey results are used by federal and state agencies to monitor the performance and adequacy of current facilities and infrastructure, and to plan for future needs.

The collection and analysis of national transportation data has been of critical importance for more than half a century. Previous surveys were conducted in 1969, 1977, 1983, 1990, 1995, 2001, 2009, 2017 and 2022. The current survey will be the tenth in this series, and allow researchers, planners, and officials at the state and federal levels to monitor travel trends.

Data from the NHTS are widely used to support research needs within the USDOT, and State and local agencies, in addition to responding to queries from Congress, the research community and the media on important issues. Current and recent topics of interest include:

- Travel to work patterns by transportation mode for infrastructure improvements and congestion reduction,
- Access to public transit, paratransit, and rail services by various demographic groups,
- Measures of travel by mode to establish exposure rates for risk analyses,
- Support for Federal, State, and local planning activities and policy evaluation,
- Active transportation by walk and bike to establish the relationship to public health issues,
- Vehicle usage for energy consumption analysis,
- Traffic behavior of specific demographic groups such as Millennials, Gen Z, and the aging population.

Within the USDOT, the Federal Highway Administration (FHWA) holds responsibility for technical and funding coordination. The National Highway Traffic Safety Administration (NHTSA), Federal Transit Administration (FTA), and the Bureau of Transportation Statistics (BTS) are also primary data users and have historically participated in project planning and financial support.

Proposed Data Acquisition Methodology

NHTS data are collected from a stratified random sample of households that represent a broad range of geographic and demographic characteristics. Letters and postcards are sent to selected households requesting some basic demographic and contact information and inviting them to participate in the diary survey. The recruitment survey is completed on the study website.

Households who complete the recruitment survey are subsequently invited to complete a diary survey. All household members aged 5 and older are eligible. The household is assigned to record their travel on a specific day and asked to note every trip taken during a 24-hour period. Based upon their preferences, the travel information is then reported through a survey website, a smartphone app., or through a telephone interview.

Reminders are sent periodically to households who do not respond within the expected timeframe. Monetary incentives are provided in increasing amounts for all households that complete the survey.

The survey will collect data during an entire 12-month period so that all 365 days of the year including weekends and holidays are accounted for. A total of 7,500 households will comprise the national sample for the 2024 survey.

Issues Related to Sampling. The sampling design reflects the U.S. household trends of decreasing landline telephone ownership and increasing access to the internet. The 2024 NextGen NHTS will leverage this shift in technology, in particular the move away from home telephone usage, to structure a research design that uses mail, web, smartphone app. and telephone data collection modes. The methodological approach starts with a national address-based sample (ABS).

The survey sample will be drawn from the ABS frame maintained by Marketing Systems Group (MSG). It originates from the U.S. Postal Service (USPS) Computerized Delivery Sequence file (CDS) and is updated on a monthly basis. MSG also provides the ability to match some auxiliary variables (*e.g.,* race/ethnicity, education, household income) to a set of sampled addresses. MSG geocodes their entire ABS frame, so block-, block group-, and tract-level characteristics from the Decennial Census and the American Community Survey (ACS) may be appended to addresses and used for sampling and/or data collection purposes.

Sample Size. Completed surveys will be obtained from a nationally representative sample of 7,500 households. Assuming response rates of 26 percent for the recruitment stage, 60 percent at the diary stage, and a residency rate of 92 percent for sampled addresses, a total of 52,258 sampled addresses will be required to attain the targeted 7,500 responding households.

Stratification. The sample will be stratified by Census Division and urban/rural classification (18 strata total). The target sample size (of responding households) will then be initially allocated among the strata according to the proportion of addresses falling in the stratum determined by the counts of addresses from the American Community Survey (ACS).

With the ABS approach, identifying targeted areas that correspond to those

for which estimates can be developed from the NHTS data are straightforward. Geocoding and GIS processing can be used to link addresses to states and counties in a highly reliable fashion. There can be some ambiguity for addresses that are P.O. boxes or are listed as rural route addresses. These can be handled in a routine manner with a set of well-defined rules as such addresses will represent only a small proportion of the population. Thus, no important issues arise in the definition of areas with an ABS sample design that relies on mail for initial contact, as is the case with the proposed approach.

Assignments for recording travel data by sampled households will be equally distributed across all days to ensure a balanced day-of-week distribution. The sample (of recruitment letters to households) will be released periodically through a process that will control the balance of travel days by month.

Data Collection Methods

An updated approach to enhancing survey response has been developed. This includes providing progressive monetary incentives and using a mail with push-to-web recruitment survey that is just 5 minutes in length. Upon completing the recruitment survey, household members aged 5 and older are offered the opportunity to provide their travel on an assigned travel day via a smartphone app. or web using a unique personal identification number (PIN) or telephone interview.

Information Proposed for Collection

Recruitment. The survey will begin with mailing the sampled households an initial invitation letter followed by postcard and letter reminders. The letter will contain a $2 cash incentive per household and promised incentives (up to $20 per person) to encourage diary completion. Participants will complete the recruitment survey on the web. The survey is designed to collect key household information (*e.g.,* enumeration of household members), basic demographic characteristics (*e.g.,* age, gender, etc.), and personal contact information (*e.g.,* email address and telephone number). To support recruitment, the study will provide a toll-free number on survey materials. The study website will provide responses to likely questions and will serve as the portal to the survey.

Diary Retrieval. The travel day diary data will be collected from respondents either from self-reporting via the web or a smartphone app., or from professionally trained interviewers using a computer-assisted telephone interviewing (CATI) system. The questionnaire and back-end systems allow for sophisticated branching and skip patterns to enhance data retrieval by asking only those questions that are necessary and appropriate for the individual participant. Look-up tables are included at the back end to assist with information such as vehicle makes and models. Google API is used to assist in identifying specific place names and locations. The location data for the participant's home, workplace, or school are stored and automatically inserted in the dataset for trips after the first report. Household rostering is a list of all vehicles and persons in the household that allows a trip to be reported from one household member and can include another household member who travel together to be inserted into the record for the second person. This automatic insert of information reduces the burden of the second respondent to be queried about a trip already reported by the initial respondent.

Data range, consistency and edit checks are automatically programmed to reduce reporting errors, survey length, and maintain the flow of information processing. Data cross checks also help reduce the burden by ensuring that the reporting is consistent within each trip.

The study website and web instrument will be reviewed for Section 508 compliance using the rules specified in sections 1194.22—'Web-based intranet and internet information and applications' and 1194.23—'Telecommunications products.' All materials will be available in both English and Spanish language forms. Spanish translations will be developed using industry standards and will apply reverse- translation protocols.

Respondents: A stratified random sample of 7,500 households across the 50 states and the District of Columbia will be included in the survey. Household will include an average of 2.5 members for a total of 18,750 individual respondents 5 years and older to the diary survey.

Frequency: This is a periodic study last conducted in 2022.

Estimated Average Burden per Response: It will take approximately 5 minutes per household member to complete the recruitment survey, and 20 minutes per eligible household member to complete the diary survey.

Estimated Total Annual Burden Hours: It is estimated that a total of 29,375 persons will complete the survey. This includes 5,000 persons in households who completed just the recruitment survey and did not participate in the diary survey and 16,125 persons who completed both the recruitment and diary surveys. This results in approximately 6,417 hours of support for this data collection effort assuming an average of 5 minutes per household for the recruitment, and 20 minutes per household member (aged 5 and older) for the diary survey.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: April 27, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–09516 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0332; FMCSA–2013–0124; FMCSA–2013–0125; FMCSA–2014–0103; FMCSA–2014–0387; FMCSA–2017–0057; FMCSA–2018–0138; FMCSA–2020–0024; FMCSA–2021–0017; or FMCSA–2022–0032]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 13 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided

below. Comments must be received on or before June 3, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2012–0332, Docket No. FMCSA–2013–0124, Docket No. FMCSA–2013–0125, Docket No. FMCSA–2014–0103, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2018–0138, Docket No. FMCSA–2020–0024, Docket No. FMCSA–2021–0017, or Docket No. FMCSA–2022–0032 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number (FMCSA–2012–0332, FMCSA–2013–0124, FMCSA–2013–0125, FMCSA–2014–0103, FMCSA–2017–0057, FMCSA–2018–0138, FMCSA–2020–0024, FMCSA–2021–0017, or FMCSA–2022–0032) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2012–0332, Docket No. FMCSA–2013–0124, Docket No. FMCSA–2013–0125, Docket No. FMCSA–2014–0103, Docket No. FMCSA–2014–0387, Docket No. FMCSA–2017–0057, Docket No. FMCSA–2018–0138, Docket No. FMCSA–2020–0024, Docket No. FMCSA–2021–0017, or Docket No. FMCSA–2022–0032), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number (FMCSA–2012–0332, FMCSA–2013–0124, FMCSA–2013–0125, FMCSA–2014–0103, FMCSA–2014–0387, FMCSA–2017–0057, FMCSA–2018–0138, FMCSA–2020–0024, FMCSA–2021–0017, or FMCSA–2022–0032) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2012–0332, FMCSA–2013–0124, FMCSA–2013–0125, FMCSA–2014–0103, FMCSA–2014–0387, FMCSA–2017–0057, FMCSA–2018–0138, FMCSA–2020–0024, FMCSA–2021–0017, or FMCSA–2022–0032) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

The 13 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these

drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 13 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 13 drivers in this notice remain in good standing with the Agency. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of May and are discussed below.

As of May 15, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 12 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Yunier Alegre (NE)
Dustin Bemesderfer (FL)
Marion Bennet (MD)
Marquarius Boyd (MS)
Stephan Gensmer (MN)
Leonie Hall (IL)
William Larson (NC)
Jonathan Ramirez (CA)
Tami Richardson-Nelson (NE)
Joseph Strassburg (SD)
Charles Whitworth (LA)
Aldale Williamson (DC)

The drivers were included in docket number FMCSA–2012–0332, FMCSA–2013–0124, FMCSA–2014–0103, FMCSA–2014–0387, FMCSA–2017–0057, FMCSA–2018–0138, FMCSA–2020–0024, FMCSA–2021–0017, or FMCSA–2022–0032. Their exemptions are applicable as of May 15, 2024 and will expire on May 15, 2026.

As of May 19, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), Michael Paasch (NE) has satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

This driver was included in FMCSA–2013–0125. The exemption is applicable as of May 19, 2024 and will expire on May 19, 2026.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must report any crashes or accidents as defined in § 390.5T; and (2) report all citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 13 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in § 391.41 (b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–09522 Filed 5–1–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to the Qualified Intermediary (QI), Withholding Foreign Partnership (WP), and Withholding Foreign Trust (WT) Application and Account Management System

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden related to the Qualified Intermediary (QI), Withholding Foreign Partnership (WP), and Withholding Foreign Trust (WT) Application and Account Management System.

DATES: Written comments should be received on or before July 1, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–1597—Public Comment Request Notice'' in the Subject line.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Qualified Intermediary (QI), Withholding Foreign Partnership (WP), and Withholding Foreign Trust (WT) Application and Account Management System.

OMB Number: 1545–1597.

Document Number: Form 14345.

Abstract: Internal Revenue Code (IRC) section 1441 (Withholding of tax on nonresident aliens), states any nonresident alien individual or of any foreign partnership shall deduct and withhold from such items a tax equal to 30 percent or 14 percent depending on circumstances. Revenue Procedure

2022–43 sets forth the final qualified intermediary (QI) withholding agreement (QI agreement) entered by the Internal Revenue Service and certain foreign persons under Treas. Reg. § 1.1441–1(e) (5) and (6). The Qualified Intermediary (QI), Withholding Foreign Partnership (WP), and Withholding Foreign Trust (WT) Application and Account Management System (QAAMS) allows entities to apply, renew, or terminate their status as a QI, WP, or WT.

Current Actions: There are no changes to the burden previously approved by OMB. This request is to extend the current approval for another 3 years.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households and Business or other for-profit.

Estimated Number of Respondents: 1,097,991.

Estimated Time per Respondent: 16 min.

Estimated Total Annual Burden Hours: 301,018.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: April 29, 2024.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2024–09567 Filed 5–1–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before June 3, 2024 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Consent for Disclosure of Non-Tax IRS Records Protected under the Privacy Act and IRS Request for Individual Access to Non-Tax Records under the Privacy Act.

OMB Number: 1545–NEW.

Form Numbers: 15293 and 15603.

Abstract: Form 15293 is used as an option to consent and approve disclosure of your non-tax IRS records. This form may be used by the parent consenting to and authorizing disclosure of the records of a minor or the legal guardian consenting to and authorizing disclosures of the records of an incompetent. Form 15603 is used to request access to non-tax records from a Privacy Act System of Records. This form may also be used by the parent seeking access to the records of a minor or the legal guardian seeking access to the records of an incompetent.

Current Actions: This form is being submitted for OMB approval.

Type of Review: New collection.

Affected Public: Individuals.

Estimated Number of Respondents: 600.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 150 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2024–09550 Filed 5–1–24; 8:45 am]

BILLING CODE 4810–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0005]

Agency Information Collection Activity Under OMB Review: Application for Dependency and Indemnity Compensation by Parent(s) (Including Accrued Benefits and Death Compensation When Applicable)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/*

PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0005''.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0005'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 1310, 38 U.S.C. 1315, 38 U.S.C. 1121, 38 U.S.C. 501(a)(2), 38 U.S.C. 5121.

Title: Application for Dependency and Indemnity Compensation by Parent(s) (Including Accrued Benefits and Death Compensation when Applicable).

OMB Control Number: 2900–0005.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21P–535 is primarily used to collect the information necessary to determine a surviving parent's eligibility for Parents' DIC benefits. The information is used to determine eligibility for VA benefits, and, if eligibility exists, the proper rate of payment.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 15268 on Friday, March 1, 2024, pages 15268.

Affected Public: Individuals or Households.

Estimated Annual Burden: 1,200 hours.

Estimated Average Burden per Respondent: 1 hour and 12 minutes (1.2 hours).

Frequency of Response: One time.

Estimated Number of Respondents: 1,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09543 Filed 5–1–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Disciplinary Appeals Board Panel

AGENCY: Department of Veterans Affairs

ACTION: Notification of Disciplinary Appeals Board Panel.

SUMMARY: The Department of Veterans Affairs (VA) Health-Care Personnel Act of 1991 revised the disciplinary grievance and appeal procedures for employees appointed under Federal law. It also required the periodic designation of VA employees who are qualified to serve on the Disciplinary Appeals Board. These employees constitute the Disciplinary Appeals Board Panel from which board members in a case are appointed. This notice announces that the roster of employees on the panel is available for review and comment. Employees, employee organizations, and other interested parties shall be provided, upon request and without charge, the list of the employees on the panel, and they may submit comments concerning the suitability of any employee on the panel list.

DATES: The names that appear on the panel roster may be selected to serve on a Disciplinary Appeals Board or as a grievance examiner after June 3, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Nicole Flood, Lead Employee Relations Specialist, Employee Relations and Performance Management Service, Office of the Chief Human Capital Officer, Department of Veterans Affairs, 810 Vermont Avenue NW, Mailstop 051, Washington, DC 20420 or *Nicole.Flood@va.gov.* Ms. Flood may be reached at 708–980–3553. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Section 203 of the Department of Veterans Affairs (VA) Health-Care Personnel Act of 1991 revised the disciplinary grievance and appeal procedures for employees appointed under Federal law. It also required the periodic designation of VA employees who are qualified to serve on the Disciplinary Appeals Board. Public Law 102–40 and 38 U.S.C. 7464(d) require that the availability of the roster be posted in the **Federal Register** periodically, but not less than annually. Requests for the panel roster and/or concerns regarding suitability for service on the panel may be emailed to *vaco051erpms@va.gov.*

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on April 25, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2024–09561 Filed 5–1–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0830]

Agency Information Collection Activity Under OMB Review: Claim for Reimbursement of Travel Expenses

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by clicking on the following link *www.reginfo.gov/public/do/PRAMain,* select ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0830.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0830'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 501(a) and 38 U.S.C. 111.

Title: Claim for Reimbursement of Travel Expenses.

OMB Control Number: 2900–0830.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 28–0968, Claim for Reimbursement of Travel Expenses serves as a request to collect information for claimants to apply for the mileage reimbursement benefit in an efficient, convenient, and accurate manner. VR&E

must determine the identity of the claimant; the dates and length of the trip being claimed, based on the claimant's residence and the place of initial evaluation, reevaluation, and counseling to include personal or vocational adjustment, training, and attendant travel, or other place in connection with vocational rehabilitation; and whether expenses other than mileage are being claimed. Once the information is obtained, it is entered into the case management system and then the form is sent to the Support Services Division (SSD) to process payment.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 11945 on Thursday, February 15, 2024, pages 11945 and 11946.

Affected Public: Individuals or Households.

Estimated Annual Burden: 27,500 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 110,000 per year.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09560 Filed 5–1–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA).

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, notice is hereby given that the VA is modifying the system of records titled, ''Investigative Database-OMI–VA'' (162VA10E1B). This system is used to document the investigative activities of the Office of the Medical Inspector (OMI).

DATES: Comments on this amended system of records must be received no later than June 3, 2024. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by the VA, the modified system of records will become effective a minimum of 30 days after date of publication in the **Federal Register**. If VA receives public comments, VA shall review the comments to determine whether any changes to the notice are necessary.

ADDRESSES: Comments may be submitted through *www.Regulations.gov* or mailed to VA Privacy Service, 810 Vermont Avenue NW, (005X6F), Washington, DC 20420. Comments should indicate that they are submitted in response to ''Investigative Database-OMI–VA'' (162VA10E1B). Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Stephania Griffin, VHA Chief Privacy Officer, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; telephone (704) 245–2492 (*Note:* this is not a toll-free number).

SUPPLEMENTARY INFORMATION: VA is amending the system of records by revising the System Number; System Location; System Manager; Purpose; Categories of Individuals Covered by the System; Categories of Records in the System; Records Source Categories; Policies and Practices for Storage of Records; Policies and Practices for Retention and Disposal of Records; Safeguards; Record Access Procedure; Contesting Records Procedures; and Notification Procedure. VA is republishing the system notice in its entirety.

The System Number is being updated from 162VA10E1B to 162VA10 to reflect the current VHA organizational routing symbol.

The System Location is being updated to remove, ''Additional records are maintained by the Austin Information Technology Center, 1615 Woodward Street, Austin, Texas 78772, and subject to their security control.''

The System Manager is being updated to replace Correspondence Analyst, with Executive Assistant.

The Purpose is being updated to remove, ''to perform statistical analysis to produce various management and follow-up reports. The data may be used for VA's extensive quality improvement programs in accordance with VA policy. In addition, the data may be used for law enforcement investigations. Survey data will be collected for the purpose of measuring and monitoring various aspects and outcomes of National, Veterans Integrated Service Network (VISN) and Facility-Level performance. Results of the survey data analysis are shared throughout the Veterans Health Administration (VHA) system.''

The Categories of Individuals Covered by the System is being updated to remove, ''their immediate family members, members of the armed services, subcontractors, consultants, volunteers.''

The Categories of Records in the System is being updated to replace 24VA10P2 with 24VA10A7. Number 3 is being removed, ''Medical benefit and eligibility information.'' Renumbering as number 4 is now number 3, and so on. Number 5 is also being removed ''Patient Satisfaction Survey Data which include questions and responses.''

The Records Source Categories is being updated to remove, ''VA Health Eligibility Center, the Food and Drug Administration, the Department of Defense, ''Income Verification Records-VA'' (89VA10NB), VA Veterans Benefits Administration automated record systems (including the ''Veterans and Beneficiaries Identification and Records Location Subsystem-VA'' (38VA23), and subsequent iterations of those systems of records.'' 24VA10P2 will be replaced with 24VA10A7 and 33VA113 will be replaced with 33VA10.

Policies and Practices for Storage of Records is being updated to remove, ''paper, magnetic tape, disk, encrypted flash memory, and laser optical media''.

Policies and Practices for Retention and Disposal of Records is being updated to include Item Numbers 1160.1 and 1160.2.

Administrative, Technical and Physical Safeguards is being updated to remove from number 4 ''an elevator card reader for floor access and a separate VHA card reader for access to the office area; and in locked storage (paper).''

Record Access Procedure is being updated to reflect the following language: ''Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above or write or visit the VA facility location where they normally receive their care. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, and describe the records sought in sufficient detail to enable VA personnel to locate them with a reasonable amount of effort.''

Contesting Records Procedures is being updated to reflect the following language, ''Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above, or may write or visit the VA facility location where they normally

receive their care. A request to contest or amend records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.''

Notification Procedure is being updated to state, ''Generalized notice is provided by the publication of this notice. For specific notice, see Record Access Procedure, above.''

The Report of Intent to Amend a System of Records Notice and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by the Privacy Act and guidelines issued by OMB, December 12, 2000.

Signing Authority

The Senior Agency Official for Privacy, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Kurt D. DelBene, Assistant Secretary for Information and Technology and Chief Information Officer, approved this document on March 26, 2024 for publication.

Dated: April 29, 2024.

Amy L. Rose,

Government Information Specialist, VA Privacy Service, Office of Compliance, Risk and Remediation, Office of Information and Technology, Department of Veterans Affairs.

SYSTEM NAME:

''Investigative Database-OMI–VA'' (162VA10).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are located at the Office of the Medical Inspector (OMI) in secure files within the OMI and indexed on a secure document management server within the Department of Veterans Affairs (VA) Central Office firewall.

SYSTEM MANAGER(S):

Official responsible for maintaining this system of records: Executive Assistant, OMI, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone 202–815–9508 (this is not a toll-free number).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

38 U.S.C. 501.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to document the investigative activities of the OMI, and to monitor the activities of VA Medical Centers in fulfilling action plans developed in response to OMI reports.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information for individuals (1) Receiving health care from the Veterans Health Administration (VHA), and (2) VHA providers that are providing the health care. Individuals encompass Veterans, current and former employees, trainees, contractors, and other individuals working collaboratively with VA.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may include information and health information related to:

1. Patient medical record abstract information including information from ''Patient Medical Record—VA'' (24VA10A7);

2. Identifying information (*e.g.,* name, birth date, death date, admission date, discharge date, gender, Social Security Number, taxpayer identification number); address information (*e.g.,* home and/or mailing address, home and/or cell telephone number, emergency contact information such as name, address, telephone number and relationship); prosthetic and sensory aid serial numbers; medical record numbers; integration control numbers; information related to medical examination or treatment (*e.g.,* location of VA medical facility providing examination or treatment, treatment dates, medical conditions treated or noted on examination); information related to military service and status;

3. Patient aggregate workload data such as admissions, discharges and outpatient visits; resource utilization such as laboratory tests, x-rays and prescriptions;

4. Data captured from various VA databases. According to VHA Directive 1038, Role of the Office of the Medical Inspector, Paragraph 4k., ''OMI, as a component of VHA, has legal authority under applicable Federal privacy laws and regulations to access and use any information, including health information, maintained in VHA records for the purposes of health care operations and health care oversight.''; and

5. Documents and reports produced and received by OMI in the course of its investigations.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans, VA employees, VA computer systems, Veterans Health Information Systems and Technology Architecture (VistA), VA medical centers, VA program offices, Veterans Integrated Service Networks (VISNs), Austin Information Technology Center, the Department of Defense, Survey of Healthcare Experiences of Patients, External Peer Review Program, and the following Systems of Records: ''Patient Medical Records-VA'' (24VA10A7) and ''National Prosthetics Patient Database-VA'' (33VA10).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To the extent that records contained in the system include information protected by 45 CFR parts 160 and 164, *i.e.,* individually identifiable health information, and 38 U.S.C. 7332, *i.e.,* medical treatment information related to drug abuse, alcoholism or alcohol abuse, sickle cell anemia or infection with the human immunodeficiency virus, that information cannot be disclosed under a routine use unless there is also specific statutory authority in 38 U.S.C. 7332 and regulatory authority in 45 CFR parts 160 and 164 permitting disclosure.

1. *Congress:* To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

2. *National Archives and Records Administration (NARA):* To the NARA in records management inspections conducted under 44 U.S.C. 2904 and 2906, or other functions authorized by laws and policies governing NARA operations and VA records management responsibilities.

3. *Department of Justice (DoJ), Litigation, Administrative Proceeding:* To the DoJ, or in a proceeding before a court, adjudicative body or other administrative body before which VA is authorized to appear, when:

(a) VA or any component thereof;

(b) Any VA employee in his or her official capacity;

(c) Any VA employee in his or her individual capacity where DoJ has agreed to represent the employee; or

(d) The United States, where VA determines that litigation is likely to affect the agency or any of its components,

is a party to such proceedings or has an interest in such proceedings, and VA determines that use of such records is relevant and necessary to the proceedings.

4. *Governmental Agencies, for VA Hiring, Security Clearance, Contract, License, Grant:* To a Federal, state, local or other governmental agency maintaining civil or criminal violation

records, or other pertinent information, such as employment history, background investigations, or personal or educational background, to obtain information relevant to VA's hiring, transfer or retention of an employee, issuance of a security clearance, letting of a contract, or issuance of a license, grant, or other benefit. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

5. *Law Enforcement:* To a Federal, State, local, territorial, Tribal or foreign law enforcement authority or other appropriate entity charged with the responsibility of investigating or prosecuting a violation or potential violation of law, whether civil, criminal, or regulatory in nature, or charged with enforcing or implementing such law, provided that the disclosure is limited to information that, either alone or in conjunction with other information, indicates such a violation. The disclosure of the names and addresses of Veterans and their dependents from VA records under this routine use must also comply with the provisions of 38 U.S.C. 5701.

6. *Attorneys Representing Clients:* To assist attorneys in representing their clients, any information in this system may be disclosed to attorneys representing subjects of investigations, including Veterans, Federal Government employees, retirees, volunteers, contractors, subcontractors or private citizens.

7. *Federal Labor Relations Authority (FLRA):* To the FLRA in connection with the investigation and resolution of allegations of unfair labor practices, the resolution of exceptions to arbitration awards when a question of material fact is raised; matters before the Federal Service Impasses Panel; and the investigation of representation petitions and the conduct or supervision of representation elections.

8. *Equal Employment Opportunity Commission (EEOC):* To the EEOC in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law.

9. *Merit Systems Protection Board (MSPB):* To the MSPB in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as otherwise authorized by law.

10. *Guardians, Courts, for Incompetent Veterans:* To a court, magistrate or administrative tribunal in matters of guardianship, inquests, and commitments; to private attorneys representing Veterans rated incompetent in conjunction with issuance of Certificates of Incompetency; or to probation and parole officers in connection with court-required duties.

11. *State Licensing Board, for Licensing:* To a Federal agency, a State or local government licensing board, the Federation of State Medical Boards, or a similar non-governmental entity that maintains records concerning individuals' employment histories or concerning the issuance, retention or revocation of licenses, certifications or registration necessary to practice an occupation, profession or specialty, to inform such non-governmental entities about the health care practices of a terminated, resigned or retired health care employee whose professional health care activity so significantly failed to conform to generally accepted standards of professional medical practice as to raise reasonable concern for the health and safety of patients in the private sector or from another Federal agency. These records may also be disclosed as part of an ongoing computer matching program to accomplish these purposes.

12. *Contractors:* To contractors, grantees, experts, consultants, students and others performing or working on a contract, service, grant, cooperative agreement or other assignment for VA, when reasonably necessary to accomplish an agency function related to the records.

13. *Federal Agencies, Fraud and Abuse:* To other Federal agencies to assist such agencies in preventing and detecting possible fraud or abuse by individuals in their operations and programs.

14. *Data Breach Response and Remediation, for VA:* To appropriate agencies, entities and persons when (1) VA suspects or has confirmed that there has been a breach of the system of records; (2) VA has determined that as a result of the suspected or confirmed breach there is a risk to individuals, VA (including its information systems, programs and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities or persons is reasonably necessary to assist in connection with VA efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.

15. *Data Breach Response and Remediation, for Another Federal Agency:* To another Federal agency or Federal entity, when VA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

16. *Office of Special Counsel:* To the Office of the Special Counsel for investigation and inquires of alleged or possible prohibited personnel practices.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained on electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, Social Security Number or other assigned identifiers of the individuals on whom they are maintained.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in this system are retained and disposed of in accordance with the schedule approved by the Archivist of the United States, VA Records Control Schedule (RCS) 10–1, Item Numbers 1160.1 and 1160.2.

ADMINISTRATIVE, TECHNICAL AND PHYSICAL SAFEGUARDS:

1. Access to and use of national administrative databases, warehouses and data marts are limited to those persons whose official duties require such access, and VA has established security procedures to ensure that access is appropriately limited. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually unique codes and passwords. VA provides information security training to all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality.

2. VA maintains Business Associate Agreements and Non-Disclosure Agreements where appropriate with contracted resources in order to maintain confidentiality of the information.

3. Physical access to computer rooms housing national administrative databases, warehouses and data marts are restricted to authorized staff and

protected by a variety of security devices. Unauthorized employees, contractors and other staff are not allowed in computer rooms. The Federal Protective Service or other security personnel provide physical security for the buildings housing computer rooms and data centers.

4. All materials containing real or scrambled Social Security numbers are kept only on secure, encrypted VHA servers, personal computers, laptops or media. All email transmissions of such files use Public Key Infrastructure (PKI) encryption. If a recipient does not have PKI, items are mailed or sent to a secure fax. Paper records containing Social Security numbers are secured in locked cabinets or offices within the OMI area. Access to OMI requires passing a security officer. All materials, both paper and electronic, that are no longer required are shredded/obliterated in accordance with VHA guidelines. Materials required for case documentation and follow up are archived in our secure document management server (electronic).

5. In most cases, copies of back-up computer files are maintained at off-site locations.

RECORD ACCESS PROCEDURES:

Individuals seeking information on the existence and content of records in this system pertaining to them should contact the system manager in writing as indicated above or write or visit the VA facility location where they normally receive their care. A request for access to records must contain the requester's full name, address, telephone number, be signed by the requester, and describe the records sought in sufficient detail to enable VA personnel to locate them with a reasonable amount of effort.

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest or amend records in this system pertaining to them should contact the system manager in writing as indicated above. A request to contest or amend records must state clearly and concisely what record is being contested, the reasons for contesting it, and the proposed amendment to the record.

NOTIFICATION PROCEDURES:

Generalized notice is provided by the publication of this notice. For specific notice, see Record Access Procedure, above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

85 FR 7404 (February 7, 2020).

[FR Doc. 2024–09529 Filed 5–1–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0079]

Agency Information Collection Activity: Employment Questionnaire

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 1, 2024.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0079'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0079'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 501, 38 U.S.C. 5317, 38 CFR 3.362 and 3.343, 38 CFR 4.16.

Title: Employment Questionnaire (VA Form 21–4140).

OMB Control Number: 2900–0079.

Type of Review: Revision of a currently approved collection.

Abstract: VA Forms 21–4140 is used to gather the necessary information to determine continued entitlement to individual unemployability. Recipients are required to certify, when requested, that the eligibility factors which established entitlement to the benefit being paid continue to exist. Individual unemployability is awarded based on a veteran's inability to be gainfully employed due to service-connected disabilities, and entitlement may be terminated if a veteran begins working. Without information about recipients' employment, VA would not be able to determine continued entitlement to individual unemployability, and overpayments would result. No changes have been made to this form. The respondent burden has increased due to the estimated number of receivables averaged over the past year.

Affected Public: Individual or Households.

Estimated Annual Burden: 285 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 3,422 per year.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–09583 Filed 5–1–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 431, et al.

Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 431, 482, 485, 495, and 512

[CMS–1808–P]

RIN 0938–AV34

Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); and make other policy-related changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 10, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1808–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1808–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1808–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov,* Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Inpatient Critical Access Hospital (CAH) Issues.

Emily Lipkin, and Jim Mildenberger, *DAC@cms.hhs.gov,* Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Lily Yuan, *NewTech@cms.hhs.gov,* New Technology Add-On Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov,* and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov,* MS–DRG Classifications Issues.

Siddhartha Mazumdar, *siddhartha.mazumdar @cms.hhs.gov*, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov,* Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, *lang.le@cms.hhs.gov,* Hospital Readmissions Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov,* Hospital Readmissions Reduction Program—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov,* Hospital-Acquired Condition Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov,* Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov,* Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov,* and Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, *elizabeth.goldstein@cms.hhs.gov,* Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Ora Dawedeit, *ora.dawedeit@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Leah Domino, *leah.domino@cms.hhs.gov,* PPS-Exempt Cancer Hospital Quality Reporting Program—Measure Issues.

Lorraine Wickiser, *lorraine.wickiser@cms.hhs.gov,* Long-Term Care Hospital Quality Reporting Program—Administration Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov,* and Elizabeth Holland, *elizabeth.holland@cms.hhs.gov,* Medicare Promoting Interoperability Program.

Bridget Dickensheets, *bridget.dickensheets@cms.hhs.gov* and Mollie Knight, *mollie.knight@cms.hhs.gov,* LTCH Market Basket Rebasing.

Benjamin Cohen, *benjamin.cohen@cms.hhs.gov,* Provider Reimbursement Review Board.

Nicholas.Bonomo@cms.hhs.gov and *tracy.smithtaylor@cms.hhs.gov,* Payment Error Rate Measurement Program.

CMMI_TEAM@cms.hhs.gov, Transforming Episode Accountability Model (TEAM).

The Clinical Standards Group, *HealthandSafetyInquiries@cms.hhs.gov,* Obstetrical Services Request for Information (RFI).

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view

public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2025 proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2025 IPPS Proposed rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2025 proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1808–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2025 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel, *DAC@cms.hhs.gov.*

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2025 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2025 proposed rule, we are proposing to continue policies to address wage index disparities impacting low wage index hospitals. We are also proposing changes relating to Medicare graduate medical education (GME) for teaching hospitals and new technology add-on payments.

We are proposing a separate IPPS payment for establishing and maintaining access to essential medicines.

In the Hospital Value-Based Purchasing (VBP) Program, we are proposing to modify scoring of the Person and Community Engagement Domain for the FY 2027 through FY 2029 program years to only score six unchanged dimensions of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, and we are proposing to adopt the updated HCAHPS Survey in the Hospital VBP Program beginning with the FY 2030 program year after the updated survey would have been publicly reported under the Hospital Inpatient Quality Reporting (IQR) Program for 1 year. We are also proposing to modify scoring on the HCAHPS Survey beginning with the FY 2030 program year to incorporate the updated HCAHPS Survey measure into nine survey dimensions. Lastly, we are providing previously and newly established performance standards for the FY 2027 through FY 2030 program years for the Hospital VBP Program.

In the Hospital IQR Program, we are proposing to add seven new measures, modify two existing measures including the HCAHPS Survey measure, and remove five measures. We are also proposing changes to the reporting and submission requirements for electronic clinical quality measures (eCQMs) and the validation process for the Hospital IQR Program data.

In the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), we are proposing to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year. We are also proposing to modify the HCAHPS Survey measure and to move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure.

In the LTCH QRP, we are proposing to add four items to the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) and modify one item on the LCDS beginning with the FY 2028 LTCH QRP. Additionally, we are proposing to extend the admission assessment window for the LCDS beginning with the FY 2028 LTCH QRP. Finally, we are seeking information on future measure concepts for the LTCH QRP and a future LTCH Star Rating system.

In the Medicare Promoting Interoperability Program, we are proposing to separate the Antimicrobial Use and Resistance (AUR) Surveillance measure into two measures, an Antimicrobial Use (AU) Surveillance measure and an Antimicrobial Resistance (AR) Surveillance measure, beginning with the electronic health record (EHR) reporting period in CY 2025. We are proposing to increase the performance-based scoring threshold from 60 to 80 points beginning with the EHR reporting period in CY 2025. We are proposing to adopt two new eCQMs and modify one eCQM, in alignment with the Hospital IQR Program. Finally, we are proposing changes to the reporting and submission requirements for eCQMs, in alignment with the Hospital IQR Program.

The Transforming Episode Accountability Model (TEAM) proposes the creation and testing of a new mandatory alternative payment model. The intent of TEAM is to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. TEAM would test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM would benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare fee-for-service (FFS) payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode. We propose to test TEAM for a 5-year model performance period, beginning January 1, 2026, and ending December 31, 2030. Under the Quality Payment Program (QPP), we anticipate that TEAM would be an Advanced Alternative Payment Model (APM)for Track 2 and Track 3 and a Merit-based Incentive Payment System (MIPS) APM for all participation tracks.

Under various statutory authorities, we either discuss continued program implementation or propose to make changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2025 and subsequent fiscal years, and

other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Section 1814(l)(4) of the Act requires downward adjustments to the applicable percentage increase, beginning with FY 2015, for CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an EHR reporting period for a payment adjustment year.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. Hospitals paid under the IPPS with approved GME programs are paid for the indirect costs of training residents in accordance with section 1886(d)(5)(B) of the Act.
- Section 1886(d)(5)(F) of the Act provides for additional Medicare IPPS payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. These payments are known as the Medicare disproportionate share hospital (DSH) adjustment. Section 1886(d)(5)(F) of the Act specifies the methods under which a hospital may qualify for the DSH payment adjustment.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(b)(3)(B)(ix) of the Act, which requires downward adjustments to the applicable percentage increase, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(n) of the Act, which establishes the requirements for an eligible hospital to be treated as a meaningful EHR user of CEHRT for an EHR reporting period for a payment adjustment year or, for purposes of subsection (b)(3)(B)(ix) of the Act, for a fiscal year.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for an additional uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act if subsection (r) did not apply (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act, in the absence of section 1886(r) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) the hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data on quality measures in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, which provides for the establishment of standardized data reporting for certain

post-acute care providers, including LTCHs.

• Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed Continuation of the Low Wage Index Hospital Policy

To help mitigate growing wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. As discussed in section III.G.5. of the preamble of this proposed rule, while we are using the FY 2021 cost report data for the FY 2025 wage index, we are unable to comprehensively evaluate the effect, if any, the low wage index hospital policy had on hospitals' wage increases during the years the COVID–19 public health emergency (PHE) was in effect. We believe it is necessary to wait until we have useable data from fiscal years after the PHE before reaching any conclusions about the efficacy of the policy. Therefore, we are proposing that the low wage index hospital policy and the related budget neutrality adjustment would be effective for at least three more years, beginning in FY 2025.

b. Proposed Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

As discussed in section V.J. of the preamble of this proposed rule, the Biden-Harris administration has made it a priority to strengthen the resilience of medical supply chains and support reliable access to products for public health, including through prevention and mitigation of medical product shortages. As a first step in this initiative, we are proposing to establish a separate payment for small, independent hospitals for the IPPS shares of the additional resource costs to voluntarily establish and maintain a 6-month buffer stock of one or more of 86 essential medicines, either directly or through contractual arrangements with a pharmaceutical manufacturer, distributor, or intermediary. For the purposes of this policy, we define small, independent hospitals as hospitals with 100 beds or fewer that are not part of a chain organization. We are proposing to make this separate payment in a non-budget neutral manner under section 1886(d)(5)(I) of the Act. We are proposing that the payment adjustments would commence for cost reporting periods beginning on or after October 1, 2024.

c. DSH Payment Adjustment, Additional Payment for Uncompensated Care, and Supplemental Payment

Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, Medicare disproportionate share hospitals (DSHs) receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that would have been paid as Medicare DSH payments under section 1886(d)(5)(F) of the Act if subsection (r) did not apply, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH that has uncompensated care will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period. This additional payment is known as the uncompensated care payment.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2025. We are also proposing to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in conjunction with more recently available data in the calculation of Factor 2. Consistent with the regulation at § 412.106(g)(1)(iii)(C)(*11*), which was adopted in the FY 2023 IPPS/LTCH PPS final rule, for FY 2025, we will use the 3 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2019, FY 2020, and FY 2021 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals.

Beginning with FY 2023 (87 FR 49047 through 49051), we also established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico. In section IV.D of the preamble of this proposed rule, we summarize the ongoing methodology for supplemental payments.

In this proposed rule, we are also proposing, for FY 2025 and subsequent fiscal years, to calculate the per-discharge amount for interim uncompensated care payments using the average of the most recent 3 years of discharge data. Accordingly, for FY 2025, we propose to use an average of discharge data from FY 2021, FY 2022, and FY 2023. We believe that our proposed approach will likely result in a better estimate of the number of discharges during FY 2025 and subsequent years for purposes of the interim uncompensated care payment calculation. We propose to codify this proposed approach in new § 412.106(i)(1).

d. Proposed Adoption of the Patient Safety Structural Measure in the Hospital IQR Program and PCHQR Program

The proposed Patient Safety Structural measure is an attestation-based measure that assesses whether hospitals have a structure and culture that prioritizes safety as demonstrated by the following five domains: (1) leadership commitment to eliminating preventable harm; (2) strategic planning and organizational policy; (3) culture of safety and learning health system; (4) accountability and transparency; and (5) patient and family engagement. Hospitals would attest to whether they engage in specific evidence-based best practices within each of these domains to achieve a score from zero to five out of five points. We are proposing that hospitals would be required to report this measure beginning with the CY 2025 reporting period/FY 2027 program year for the PCHQR Program and for the CY 2025 reporting period/FY 2027 payment determination for the Hospital IQR Program.

e. Proposed Updated Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure in the Hospital IQR Program, Hospital VBP Program, and PCHQR Program

The proposal to use the updated version of the HCAHPS Survey measure aligns with the National Quality Strategy goal to bring patient voices to the forefront by incorporating feedback from patients and caregivers. The proposed updated HCAHPS Survey measure would be adopted for the Hospital IQR and PCHQR Programs beginning with the CY 2025 reporting period/FY 2027 payment determination and the CY 2025 reporting period/FY 2027 program year, respectively. For the Hospital VBP Program, we are proposing to modify scoring on the Person and Community Engagement Domain for the FY 2027 through FY 2029 program years to only score six unchanged dimensions of the HCAHPS Survey. We are proposing to adopt the updated HCAHPS Survey measure beginning with the FY 2030 program year, which would result in nine HCAHPS Survey dimensions for the Person and Community Engagement Domain. We are also proposing to modify scoring of the Person and Community Engagement Domain beginning with the FY 2030 program year to account for the proposed updates to the HCAHPS Survey.

f. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this proposed rule, we are proposing to modify scoring on the Person and Community Engagement Domain for the FY 2027 through FY 2029 program years while the updated HCAHPS Survey measure would be publicly reported under the Hospital IQR Program. In addition, we are proposing to adopt the updated HCAHPS Survey measure beginning with the FY 2030 program year and modify scoring beginning with the FY 2030 program year to account for the updated HCAHPS Survey.

g. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase. In the FY 2025 IPPS/LTCH PPS proposed rule, we are proposing several changes to the Hospital IQR Program. We are proposing the adoption of seven new measures: (1) Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (2) Age Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (3) Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations beginning with the CY 2026 reporting period/FY 2028 payment determination; (4) Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations beginning with the CY 2026 reporting period/FY 2028 reporting period; (5) Hospital Harm—Falls with Injury eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; (6) Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; and (7) Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination. We are also proposing refinements to two measures currently in the Hospital IQR Program measure set: (1) Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination; and (2) the HCAHPS Survey beginning with the CY 2025 reporting period/FY 2027 payment determination. We are also proposing the removal of five measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 27 payment determination ; (2) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (3) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (4) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN) measure beginning with July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination and (5) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2021–March 31, 2024 reporting period/FY 2026 payment determination.

We are proposing to modify eCQM data reporting and submission requirements by proposing a progressive increase in the number of mandatory eCQMs a hospital would be required to report on beginning with the CY 2026 reporting period/FY 2028 payment determination. We are also proposing two changes to current policies related to validation of hospital data: (1) to implement eCQM validation scoring based on the accuracy of eCQM data beginning with the validation of CY 2025 eCQM data affecting the FY 2028 payment determination; and (2) modification of the data validation reconsideration request requirements to make medical records submission optional for reconsideration requests beginning with CY 2023 discharges/FY 2026 payment determination.

h. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. In the FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year. We are also proposing to modify the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 program year. We are also proposing to move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure from July 2026 to January 2026 or as soon as feasible thereafter.

i. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

We are proposing the following changes to the LTCH QRP: (1) add four items to the LCDS beginning with the FY 2028 LTCH QRP; (2) modify one item on the LCDS beginning with the FY 2028 LTCH QRP; and (3) extend the admission assessment window for the LCDS beginning with the FY 2028 LTCH QRP. We are also seeking information on future measure concepts for the

LTCH QRP and a future LTCH Star Rating system.

j. Medicare Promoting Interoperability Program

In section X.F. of the preamble of this proposed rule, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) to separate the Antimicrobial Use and Resistance (AUR) Surveillance measure into two measures, an Antimicrobial Use (AU) Surveillance measure and an Antimicrobial Resistance (AR) Surveillance measure, beginning with the EHR reporting period in CY 2025; to add a new exclusion for eligible hospitals or critical access hospitals (CAHs) that do not have a data source containing the minimal discrete data elements that are required for AU or AR Surveillance reporting; to modify the applicability of the existing exclusions to either the AU or AR Surveillance measures, respectively; and to treat the AU and AR Surveillance measures as new measures with respect to active engagement beginning with the EHR reporting period in CY 2025; (2) to increase the performance-based scoring threshold for eligible hospitals and CAHs reporting under the Medicare Promoting Interoperability Program from 60 points to 80 points beginning with the EHR reporting period in CY 2025; (3) to adopt two new eCQMs that hospitals can select as one of their three self-selected eCQMs beginning with the CY 2026 reporting period: the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM; (4) beginning with the CY 2026 reporting period, to modify one eCQM, the Global Malnutrition Composite Score eCQM; and (5) to modify eCQM data reporting and submission requirements by proposing a progressive increase in the number of mandatory eCQMs eligible hospitals and CAHs would be required to report on beginning with the CY 2026 reporting period.

k. Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)

In this proposed rule, we are including a proposal to implement section 4122 of the CAA, 2023. Section 4122(a) of the CAA, 2023, amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of additional residency positions (also referred to as slots) to hospitals. We refer readers to section V.F.2. of the preamble of this proposed rule for a summary of the provisions of section 4122 of the CAA, 2023 that we are proposing to implement in this proposed rule.

l. Extension of the Medicare-Dependent, Small Rural Hospital (MDH) Program and the Temporary Changes to the Low-Volume Hospital Payment Adjustment

The Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program and the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for a portion of FY 2025. Specifically, section 306 of the CAA, 2024 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) of the Act through December 31, 2024. Section 307 of the CAA, 2024 extended the MDH program under section 1886(d)(5)(G) of the Act through December 31, 2024. Prior to enactment of the CAA, 2024, the low-volume hospital qualifying criteria and payment adjustment were set revert to the statutory requirements that were in effect prior to FY 2011 at the end of FY 2024 and beginning October 1, 2024, the MDH program would have no longer been in effect.

We recognize the importance of these extensions with respect to the goal of advancing health equity by addressing the health disparities that underlie the health system is one of CMS' strategic pillars [1] and a Biden-Harris Administration priority.[2] These provisions are projected to increase payments to IPPS hospitals by approximately $137 million in FY 2025.

m. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we propose the Transforming Episode Accountability Model (TEAM). TEAM would be a 5-year mandatory model tested under the authority of section 1115A of the Act, beginning on January 1, 2026, and ending on December 31, 2030. The intent of TEAM is to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. TEAM would test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

Under Traditional Medicare, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, providers may not be incentivized to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. By holding hospitals accountable for all items and services provided during an episode, providers would be better incentivized to coordinate patient care, avoid duplicative or unnecessary services, and improve the beneficiary care experience during care transitions.

Under the TEAM proposals, all acute care hospitals, with limited exceptions, located within the Core-Based Statistical Areas that CMS selects for model implementation would be required to participate in TEAM. As proposed, TEAM would have a 1-year glide path opportunity that would allow TEAM participants to ease into full financial risk as well as different participation tracks to accommodate different levels of financial risk and reward. Episodes would include non-excluded Medicare Parts A and B items and services and would begin with an anchor hospitalization or anchor procedure and would end 30 days after hospital discharge. We are proposing that the following episode categories, when furnished by a TEAM participant, would initiate a TEAM Episode: lower extremity joint replacement, surgical hip femur fracture treatment, spinal fusion, coronary artery bypass graft, and major bowel procedure.

TEAM participants would continue to bill Medicare FFS as usual but would receive target prices for episodes prior to each performance year. Target prices would be based on 3 years of baseline data, prospectively trended forward to the relevant performance year, and calculated at the level of MS–DRG/HCPCS episode type and region. Target prices would also include a discount factor, normalization factor, and a risk-adjustment. Performance in the model would be assessed by comparing TEAM participants' actual Medicare FFS spending during a performance year to their reconciliation target price as well as by assessing performance on three quality measures. TEAM participants would earn a payment from CMS, subject to a quality performance

[1] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

[2] *https://www.whitehouse.gov/priorities/.*

adjustment, if their spending is below the reconciliation target price. TEAM participants would owe CMS a repayment amount, subject to a quality performance adjustment, if their spending was above the reconciliation target price.

n. Maternity Care Request for Information (RFI)

In alignment with our commitment to addressing the maternal health crisis, this RFI seeks to gather information on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients as compared to non-Medicare patients. To the extent that the resources required differ between patient populations, we also wish to gather information on the extent to which non-Medicare payers, or other commercial insurers may be using the IPPS as a basis for determining their payment rates for inpatient pregnancy and childbirth services and the effect, if any, that the use of the IPPS as a basis for determining payment by those payers may have on maternal health outcomes.

o. Obstetrical Services RFI

As a result of ongoing concerns about the provision of maternity care in Medicare and Medicaid certified hospitals, CAHS, and REHs, this proposed rule includes a request for information regarding our intent to propose baseline health and safety standards for obstetrical services in future rulemaking. Public comments on the FY 2023 IPPS/LTCH PPS proposed rule maternal health request for information recommended that CMS explore options to establish an Obstetrical Services condition of participation (CoP) for participating hospitals in collaboration with relevant stakeholders. With this RFI, we hope to further explore such options as we develop a proposal for a targeted Obstetrical Services CoP. We are seeking public comment on multiple detailed questions, ultimately seeking potential solutions that can be implemented through the hospital CoPs to address well-documented concerns regarding maternal morbidity, mortality, and access in the United States. The goal is to ensure that any policy changes improve maternal health care outcomes, addresses unjust disparities in care, and do not exacerbate access to care issues.

p. Conditions of Participation Requirements for Hospitals and Critical Access Hospitals To Report Acute Respiratory Illnesses

In section X.F. of the preamble of this proposed rule, we are proposing to update the hospital and CAH infection prevention and control and antibiotic stewardship programs conditions of participation (CoPs) to extend a limited subset of the current COVID–19 and influenza data reporting requirements. These proposed reporting requirements ensure that hospitals and CAHs have appropriate insight related to evolving infection control needs. Specifically, CMS is proposing to replace the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs with a new standard addressing acute respiratory illnesses to require that, beginning on October 1, 2024, hospitals and CAHs would have to electronically report information about COVID–19, influenza, and RSV. CMS is proposing that outside of a public health emergency (PHE), hospitals and CAHs would have to report these data on a weekly basis.

q. Proposed Changes to the Severity Level Designation for Z Codes Describing Inadequate Housing and Housing Instability

As discussed in section II.C. of the preamble of this proposed rule, we are proposing to change the severity level designation for the social determinants of health (SDOH) diagnosis codes describing inadequate housing and housing instability from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) for FY 2025. Consistent with our annual updates to account for changes in resource consumption, treatment patterns, and the clinical characteristics of patients, CMS is recognizing inadequate housing and housing instability as indicators of increased resource utilization in the acute inpatient hospital setting.

Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [1] we also continue to be interested in receiving feedback on how we might further foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.2. of the preamble of this proposed rule.

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[1] *Available at* 86 FR 7009 (January 25, 2021) (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Continuation of the Low Wage Index Hospital Policy	We are proposing to continue the low wage index hospital policy and the related budget neutrality adjustment for at least 3 years beginning in FY 2025.
Proposed Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines	We are proposing to make an IPPS payment adjustment for the additional resource costs that small, independent hospitals incur in establishing and maintaining access to a 6-month buffer stock of one or more essential medicine(s) beginning in FY 2025. This proposed payment adjustment would not be budget neutral. We estimate that 493 hospitals would qualify under our proposal. We estimate that the cost to those hospitals to establish buffer stocks of essential medicines would, in aggregate summed across all 493 hospitals, be approximately $2.8 million. Under our proposal, Medicare would pay its share of those costs (approximately 11 percent of that amount, or $0.3 million).
Uncompensated Care Payments	For FY 2025, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue using uninsured estimates produced by OACT as part of the development of the NHEA in the calculation of Factor 2. As provided in the regulation at § 412.106(g)(1)(iii)(C)(*11*), for FY 2025, we are proposing to use the 3 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2019, FY 2020, and FY 2021 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals.
Proposed Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience an increase of approximately $3.2 billion in FY 2025, primarily driven by the changes in FY 2025 operating payments and capital payments and the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program on January 1, 2025.
Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, based on the best available data for the 330 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum of this proposed rule, which reflect the proposed update to the LTCH PPS standard Federal payment rate for FY 2025, would result in an estimated increase in payments in FY 2025 of approximately $41 million.
Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)	Section 4122(a) of the CAA, 2023 amended section 1886(h) of the Act by adding a new paragraph 1886(h)(10) requiring the distribution of additional residency positions (also referred to as slots) to hospitals. We refer readers to section V.J.2. of this proposed rule for a summary of the provisions of section 4122 that we are proposing to implement in this proposed rule. We estimate that the proposal we present in the preamble of this proposed rule to implement section 4122 of the CAA, 2023 would result in an estimated cost of approximately $10 million for FY 2026.
Changes to the Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2025 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2025 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2025 discharges is approximately $1.7 billion.
Changes to the Hospital IQR Program	Across 3,050 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program would result in a total information collection burden increase of 40,019 hours at a cost increase of $1,274,980 associated with our proposed policies across a 3-year period from the CY 2025 reporting period/FY 2027 payment determination through the CY 2027 reporting period/FY 2029 payment determination.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Changes to the PCHQR Program	Across 11 PCHs, we estimate that our proposed changes for the PCHQR Program would result in a total information collection burden increase of 166 hours at a cost increase of $4,047 beginning with the CY 2025 reporting period/FY 2027 program year.
Changes to the LTCH QRP	Across 329 LTCHs, we estimate that our proposed changes for the LTCH QRP would result in a total information collection burden increase of 116.55 hours associated with our policies and updated burden estimates and a total cost increase of approximately $138,231.88 for the FY 2028 LTCH QRP.
Changes to the Medicare Promoting Interoperability Program	Across 4,550 eligible hospitals and CAHs, we estimate that our proposed changes for the Medicare Promoting Interoperability Program would result in an increase of 5,038 hours at a cost increase of $262,581 to the information collection burden for the EHR reporting period in CY 2027 and subsequent years.
Transforming Episode Accountability Model (TEAM)	We estimate that testing TEAM would result in saving the Medicare program $705 million across the 5 performance years.
CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses	Across 6,384 hospitals and CAHs, we estimate that our proposed changes would result in 248,976 hours and a total cost of $19,420,128 for the weekly reporting, which is $3,042 per facility yearly. We estimate for PHE reporting, if declared by the secretary, Low to high hours range 1,005,480 to 3,495,240 and total cost ranging from $ 78,427,440 to S 272,628,720 depending on the frequency of reporting required.
Proposed Changes for the Add-On Payments for New Services and Technologies	As discussed in Appendix A of this proposed rule, we are proposing to change the April 1 cutoff to October 1 for determining whether a technology would be within its 2- to 3-year newness period. If we determine that all 10 of the FY 2025 new technology add-on payment applications that have been FDA-approved or cleared since the start of FY 2024 meet the specified criteria for new technology add-on payments and if we determine that none of these for technologies would be substantially similar to those technologies that were first approved for new technology add-on payments prior to FY 2025, based on preliminary information from the applicants at the time of this proposed rule, this proposal would increase IPPS spending by approximately $380 million in FY 2027. We are also proposing to no longer consider a hold status to be an inactive status for the purposes of eligibility for the new technology add-on payment. We note that the cost impact of this proposal is not estimable. We expect that some applicants who were ineligible to apply in FY 2025 may apply for new technology add-on payments for FY 2026. Finally, we are proposing, for certain gene therapies for the treatment of sickle cell disease, we will temporarily increase the new technology add-on payment percentage to 75 percent. We note that it is premature to estimate the potential payment impact for FY 2025 because we have not yet determined whether any gene therapy indicated and used specifically for the treatment of SCD will meet the specified criteria for new technology add-on payments for FY 2025.

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B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for an additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

With the recent enactment of section 307 of the CAA, 2024, under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through December 31, 2024. For discharges occurring on or after October 1, 2007, but before January 1, 2025, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 307 of the CAA, 2024 extended the MDH program through the first quarter of FY 2025 only, beginning on January 1, 2025, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond December 31, 2024, beginning January 1, 2025, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin

Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals. The additional payment is based on the indirect medical education (IME) adjustment factor, which is calculated using a hospital's ratio of residents to beds and a multiplier, which is set by Congress. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. The regulations regarding the indirect medical education (IME) adjustment are located at 42 CFR 412.105.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. The Consolidated Appropriations Act, 2023 (CAA 2023; Pub. L. 117–328)

Section 4122 of the CAA, 2023, amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of additional residency positions (also referred to as slots) to hospitals. Section 1886(h)(10)(A) of the Act requires that for FY 2026, the Secretary shall initiate an application round to distribute 200 residency positions. At least 100 of the positions made available under section 1886(h)(10)(A) of the Act shall be distributed for psychiatry or psychiatry subspecialty residency training programs. The Secretary is required, subject to certain provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31, 2026, and the increase is effective beginning July 1, 2026.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(10)(B)(i) of the Act requires the Secretary to take into account the ''demonstrated likelihood'' of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(10)(B)(ii) of the Act requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals. Stated briefly, and discussed in greater detail later in this proposed rule, the categories are as follows: (1) hospitals located in rural areas or that are treated as being located in a rural area (pursuant to sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act); (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in States with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Section 1886(h)(10)(F)(iii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(10)(B)(iii) of the Act further requires that each qualifying hospital that submits a timely application receive at least 1 (or a fraction of 1) of the residency positions made available under section 1886(h)(10) of the Act before any qualifying hospital receives more than 1 residency position.

Section 1886(h)(10)(C) of the Act places certain limitations on the distribution of the residency positions.

First, a hospital may not receive more than 10 additional full-time equivalent (FTE) residency positions. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the hospital agrees to increase the total number of FTE residency positions under the approved medical residency training program of the hospital by the number of positions made available to that hospital. Third, if a hospital that receives an increase to its otherwise applicable resident limit under section 1886(h)(10) of the Act is eligible for an increase to its otherwise applicable resident limit under 42 CFR 413.79(e)(3) (or any successor regulation), that hospital must ensure that residency positions received under section 1886(h)(10) of the Act are used to expand an existing residency training program and not for participation in a new residency training program.

2. The Consolidated Appropriations Act, 2024 (CAA, 2024; Pub. L. 118–42)

Section 306 of the CAA, 2024 extended through the first 3 months of FY 2025 the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals in effect for FYs 2019 through 2024. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2024 and the portion of FY 2025 occurring before January 1, 2025, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through December 31, 2024, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

Section 307 of the CAA, 2024 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through the first 3 months of FY 2025 (that is, through December 31, 2024).

D. Summary of the Proposed Provisions

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2025 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2025.

The following is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2025.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2025 status of new technologies approved for add-on payments for FY 2024, a presentation of our evaluation and analysis of the FY 2025 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. 108–173, obtained in a town hall meeting for applications not submitted under an alternative pathway), and a discussion of the proposed status of FY 2025 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to change the April 1 cutoff to October 1 for determining whether a technology would be within its 2- to 3-year newness period when considering eligibility for new technology add-on payments, beginning in FY 2026, effective for those technologies that are approved for new technology add-on payments starting in FY 2025 or a subsequent years (as discussed in II.E.7. of the preamble of this proposed rule).
- A proposal that, beginning with new technology add-on payment applications for FY 2026, we will no longer consider a hold status to be an inactive status for the purposes of eligibility for the new technology add-on payment (as discussed in section II.E.8. of the preamble of this proposed rule).
- A proposal that, subject to our review of the new technology add-on payment eligibility criteria, for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH final rule for the treatment of sickle cell disease (SCD), effective with discharges on or after October 1, 2024, and concluding at the end of the 2- to 3-year newness period for such therapy, we will temporarily increase the new technology add-on payment percentage to 75 percent (as discussed in section II.E.9. of the preamble of this proposed rule).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule, we propose revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- Proposed changes in CBSAs as a result of new OMB labor market area delineations and proposed policies related to the proposed changes in CBSAs.
- The proposed FY 2025 wage index update using wage data from cost reporting periods beginning in FY 2019.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2025 based on the 2022 Occupational Mix Survey.
- Proposed application of the rural, imputed and frontier State floors, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2025 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the FY 2025 wage index.

3. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2025

In section IV. of the preamble of this proposed rule, we discuss the following:

- Proposed calculation of Factor 1 and Factor 2 of the uncompensated care payment methodology.
- Proposed methodological approach for determining Factor 3 of the uncompensated care payment for FY 2025, which is the same methodology that was used for FY 2024.
- Proposed methodological approach for determining the amount of interim uncompensated care payments using the average of the most recent 3 years of discharge data.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2025.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status and clarification of the qualification under the discharge criterion for osteopathic hospitals.
- Proposed implementation of the statutory extension of the temporary changes to the low-volume hospital payment adjustment through December 31, 2024, the statutory expiration beginning January 1, 2025, and the proposed payment adjustments for low-volume hospitals for FY 2025.
- Proposed implementation of the statutory extension of the MDH program through December 31, 2024, and the statutory expiration beginning January 1, 2025.
- A proposal to implement a provision of the Consolidated Appropriations Act relating to payments to hospitals for GME and IME costs, proposed direct graduate medical education (GME) and indirect medical education (IME) policy modifications to the criteria for new residency programs; technical fixes to the DGME regulations; a notice of closure of two teaching hospitals and opportunities to apply for available slots and a reminder of core-based statistical area (CBSA) changes and application to GME policies;.
- Proposed nursing and allied health education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CY 2023.
- Proposed update to the payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

Proposed separate IPPS payment for establishing and maintaining access to essential medicines.

- Updating the proposed estimate of the financial impacts for the FY 2025 Hospital Readmissions Reduction Program.
- Proposed modifications to the scoring of the Person and Community Engagement Domain in the Hospital VBP Program.

++ For the FY 2027 through FY 2029 program years to only score on six unchanged dimensions of the HCAHPS Survey.

++ Beginning with the FY 2030 program year to account for the proposed updated HCAHPS Survey.

- Updating the proposed estimate of the financial impacts for the FY 2025 Hospital-Acquired Conditions Reduction Program.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2025.

5. Proposed FY 2025 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble of the proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2025.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of the proposed rule, we discuss the following:

- Proposed changes to payments to certain excluded hospitals for FY 2025.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we propose to rebase and revise the LTCH market basket to reflect a 2022 base year, which includes a proposed update to the LTCH PPS labor-related share. In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2025. We are also proposing a technical clarification to the regulations for hospitals seeking to be classified as an LTCH.

8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed the following:

- Solicitation of comment on adopting measures across the hospital quality reporting and value-based purchasing programs which capture more forms of unplanned post-acute care and encourage hospitals to improve discharge processes.
- Proposed changes to the requirements for the Hospital IQR Program.
- Proposed changes to the requirements for the PCHQR Program.
- Proposed adoption of the Patient Safety Structural measure in the Hospital IQR Program and the PCHQR Program.
- Proposed updated HCAHPS Survey measure in the Hospital IQR Program, PCHQR Program, and Hospital VBP Program.
- Proposed changes to the requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and request for information on future measure concepts for the LTCH QRP and a star rating system for the LTCH QRP.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

9. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section X. of the preamble of the proposed rule includes the following:

- Proposed implementation of TEAM that would test whether an episode-based pricing methodology linked with accountability for quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries.
- Proposed changes to permit a Provider Reimbursement Review Board (PRRB) member to serve up to 3 consecutive terms (9 consecutive years total), and up to 4 consecutive terms (12 consecutive years total) in cases where a PRRB Member who, in their second or third consecutive term, is designated as Chairperson, to continue serving as Chairperson in the fourth consecutive term.
- Solicitation of comments to gather information on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients as compared to non-Medicare patients.
- Solicitation of comments to gather information on potential solutions that can be implemented through the hospital CoPs to address well-documented concerns regarding maternal morbidity, mortality, disparities, and maternity care access in the United States.
- Proposal to remove the exclusion of Puerto Rico from the Payment Error Rate Measurement (PERM) program found at 42 CFR 431.954(b)(3).
- Proposal for a new hospital CoP to replace the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs that were created during PHE.

10. Other Provisions of the Proposed Rule

Section XI.A. of the preamble of the proposed rule includes our discussion of the MedPAC Recommendations.

Section XI.B. of the preamble of the proposed rule includes a descriptive listing of the public use files associated with this proposed rule.

Section XII. of the preamble of the proposed rule includes the collection of information requirements for entities based on our proposals.

Section XIII. of the preamble of the proposed rule includes information regarding our responses to public comments.

11. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2025 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum of the proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2025 for certain hospitals excluded from the IPPS.

12. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2025 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2025. We are proposing to establish the adjustments for the wage index (including proposed changes to the LTCH PPS labor market area delineations based on the new OMB delineations), labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

13. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs and other entities.

14. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2025 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2024 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2024 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov.*

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2024 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085; 83 FR 41158 through 41258; 84 FR 42058 through 42165; 85 FR 58445 through 58596; 86 FR 44795 through 44961; 87 FR 48800 through 48891; and 88 FR 58654 through 58787, respectively).

For discussion regarding our previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48799 through 48800).

C. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2025 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding

System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for Proposed FY 2025 MS–DRG Updates

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28127) and final rule (87 FR 48800 through 48801), beginning with FY 2024 MS–DRG classification change requests, we changed the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. We also described the new process for submitting requested changes to the MS–DRGs via a new electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), accessed at *https://mearis.cms.gov.* We stated that effective with FY 2024 MS–DRG classification change requests, CMS will only accept requests submitted via MEARIS™ and will no longer consider requests sent via email. Additionally, we noted that within MEARIS™, we have built in several resources to support users, including a ''Resources'' section available at *https://mearis.cms.gov/public/resources* with technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'', also at the bottom of the MEARIS™ site. Accordingly, interested parties had to submit MS–DRG classification change requests for FY 2025 by October 20, 2023.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the request for MS–DRG classification changes to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA) of 1995 and approved under OMB control number 0938–1431 and has an expiration date of 09/30/2025.

Interested parties should submit any MS–DRG classification change requests, including any comments and suggestions for FY 2026 consideration by October 20, 2024 via MEARIS™ at: *https://mearis.cms.gov/public/home.*

As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking.

We received four requests to modify the GROUPER logic in a number of cardiac MS–DRGs under Major Diagnostic Category (MDC) 05 (Diseases and Disorders of the Circulatory System). Specifically, we received requests to—

- Modify the GROUPER logic of new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) to be defined by cases reporting procedure codes describing a single open mitral or aortic valve replacement/repair (MVR or AVR) procedure, plus an open coronary artery bypass graft procedure (CABG) or open surgical ablation or cardiac catheterization procedure plus a second concomitant procedure.
- Modify the GROUPER logic of new MS–DRG 212 by redefining the procedure code list that describes the performance of a cardiac catheterization by either removing the ICD–10–PCS codes that describe plain radiography of coronary artery codes from the logic list or adding ICD–10–PCS procedure codes that involve computed tomography (CT) or magnetic resonance imaging (MRI) scanning using contrast to the list. This requestor also suggested that CMS add ICD–10–PCS procedures codes that describe endovascular valve replacement or repair procedures into the GROUPER logic of MS–DRG 212.
- Modify the GROUPER logic of new MS–DRGs 323, 324 and 325 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC, without MCC, and without Intraluminal Device, respectively). In two separate but related requests, the requestors suggested that we add procedure codes that describe additional percutaneous coronary intervention (PCI) procedures such as percutaneous coronary rotational, laser, and orbital atherectomy to the GROUPER logic of new MS–DRGs 323, 324, and 325.

We appreciate the submissions and related analyses provided by the requestors for our consideration as we review MS–DRG classification change requests for FY 2025; however, we note the complexity of the GROUPER logic for these MS–DRGs in connection with these requests requires more extensive analyses to identify and evaluate all of the data relevant to assessing these potential modifications. Specifically, we note the list of procedure codes that describe the performance of a cardiac catheterization is in the definition of multiple MS–DRGs in MDC 05. Analyzing the impact of revising this list necessitates evaluating the impact across numerous other MS–DRGs in MDC 05 that also include this list in their definition, in addition to new MS–DRG 212. Secondly, as discussed further in section II.C.4.c of this proposed rule, our analysis continues to indicate that, when performed, open cardiac valve replacement and supplement procedures are clinically different from endovascular cardiac valve replacement and supplement procedures in terms of technical complexity and hospital resource use. Lastly, as we have stated in prior rule making (88 FR 58708), atherectomy is distinct from coronary lithotripsy in that each of these procedures are defined by clinically distinct definitions and objectives. Additional analysis to assess for unintended consequences across the classification is needed as we have made a distinction between the root operations used to describe atherectomy (Extirpation) and the root operation used to describe lithotripsy (Fragmentation) in evaluating other requests in rulemaking. We will need to consider the application of these two root operations in other scenarios where we have also specifically stated that Extirpation is not the same as Fragmentation and do not warrant similar MS–DRG assignment (85 FR 58572 through 58573). Furthermore, as MS–DRG 212 and MS–DRGs 323, 324 and 325 recently became effective on October 1, 2023 (FY 2024), we believe additional time is needed to review and evaluate extensive modifications to the structure of these MS–DRGs.

We will continue to monitor the data as we consider these issues in connection with future rulemaking. As we continue the analysis of the claims data with respect to MS–DRGs in MDC 05, we welcome public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs. Feedback and other suggestions may be directed to MEARIS™ at: *https://mearis.cms.gov/public/home.* As noted, interested parties should submit any MS–DRG classification change requests, including any comments and suggestions for FY 2026 consideration by October 20, 2024 via MEARIS™ at: *https://mearis.cms.gov/public/home.*

As we did for the FY 2024 IPPS/LTCH PPS proposed rule, for this FY 2025

IPPS/LTCH PPS proposed rule we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 42, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2025. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2025 as reflected in Table 6A.—New Diagnosis Codes—FY 2025 and Table 6B.—New Procedure Codes—FY 2025 associated with this proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2025 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2025, and Table 6D.—Invalid Procedure Codes—FY 2025 associated with this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. Because the diagnosis codes no longer valid for FY 2025 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a and 6P.1b that includes the mapped Version 42 FY 2025 ICD–10–CM and ICD–10–PCS codes and the deleted Version 41 FY 2024 ICD–10–CM codes and V41.1 ICD–10–PCS codes that should be used for testing purposes with users' available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this proposed rule. In addition, users will be able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 42.

We also note that in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58764), we stated that, as discussed in the CY 2024 Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) proposed rule (CY 2024 OPPS/ASC proposed rule) (88 FR 49552, July 31, 2023), consistent with the process that is used for updates to the ''Integrated'' Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, we proposed to address any future revisions to the IPPS Medicare Code Editor (MCE), including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. As discussed in the CY 2024 OPPS/ASC proposed rule, we proposed to remove discussion of the IPPS MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the Medicare administrative contractors (MACs). We encouraged readers to review the discussion in the CY 2024 OPPS/ASC proposed rule and submit comments in response to the proposal by the applicable deadline by following the instructions provided in that proposed rule.

In the CY 2024 OPPS/ASC final rule (88 FR 82121 through 82124), after consideration of the public comments we received, we finalized the proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs. Beginning with FY 2025, in association with the annual proposed rule, we are making available a draft version of the Definitions of Medicare Code Edits (MCE) Manual to provide the public with an opportunity to review any changes that will become effective October 1 for the upcoming fiscal year. In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, any further changes to the MCE will be reflected in the finalized Definitions of Medicare Code Edits (MCE) Manual, made available in association with the annual final rule. We are making available the draft FY 2025 ICD–10 MCE Version 42 Manual file on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

The MCE manual is comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. The public may submit any questions, comments, concerns, or recommendations regarding the MCE to the CMS mailbox at *MSDRGClassificationChange@cms.hhs.gov* for our review and consideration.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 42, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 42, the draft version of the Definitions of Medicare Code Edits Manual, Version 42, and the supplemental mapping files in Table 6P.1a and 6P.1b of the FY 2024 and FY 2025 ICD–10–CM diagnosis and ICD–10–PCS procedure codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

Following are the changes that we are proposing to the MS–DRGs for FY 2025. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. For this FY 2025 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2023 update of the FY 2023 MedPAR file, which contains hospital bills received from October 1, 2022 through September 30, 2023. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''September 2023 update of the FY 2023 MedPAR file.''

In deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication

or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798), we finalized a delay in applying this technical criterion to existing MS–DRGs until FY 2023 or future rulemaking, in light of the public health emergency (PHE). Interested parties recommended that a complete analysis of the MS–DRG changes to be proposed for future rulemaking in connection with the expanded three-way severity split criteria be conducted and made available to enable the public an opportunity to review and consider the redistribution of cases, the impact to the relative weights, payment rates, and hospital case mix to allow meaningful comment prior to implementation.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48803), we also finalized a delay in application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split in light of the ongoing PHE and until such time additional analyses can be performed to assess impacts, as discussed in response to public comments in the FY 2022 and FY 2023 IPPS/LTCH PPS final rules.

In association with our discussion of application of the NonCC subgroup criteria in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26673 through 26676), we provided an alternate test version of the ICD–10 MS–DRG GROUPER Software, Version 41.A, reflecting the proposed GROUPER logic for FY 2024 as modified by the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* Therefore, users had access to the alternate test software allowing them to build case examples that reflect the proposals included in the proposed rule with application of the NonCC subgroup criteria. We also provided additional files including an alternate Table 5—Alternate List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay, an alternate Length of Stay (LOS) Statistics file, an alternate Case Mix Index (CMI) file, and an alternate After Outliers Removed and Before Outliers Removed (AOR_BOR) file. The files are available in association with the FY 2024 IPPS/LTCH PPS proposed rule on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

We stated that the alternate test software and additional files were made available so that the public could better analyze and understand the impact on the proposals included in the proposed rule if the NonCC subgroup criteria were to be applied to existing MS–DRGs with a three-way severity level split. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26673 through 26676) for further discussion of the alternate test software and additional files that were made available.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58655 through 58661), we finalized to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024. We stated that we would continue to review and consider the feedback we had received in response to the additional information we made available in association with the FY 2024 IPPS/LTCH PPS proposed rule for our development of the FY 2025 proposed rule.

We note that the IPPS Payment Impact File made available in connection with our annual IPPS rulemakings includes information used to categorize hospitals by various geographic and special payment consideration groups, including geographic location (urban or rural), teaching hospital status (that is, whether or not a hospital has GME residency programs and receives an IME adjustment), DSH hospital status (that is, whether or not a hospital receives Medicare DSH payments), special payment groups (that is, SCHs, MDHs, and RRCs) and other categories reflected in the impact analysis generally shown in Appendix A of the annual IPPS rulemakings. The IPPS Payment Impact File associated with the FY 2024 IPPS/LTCH PPS final rule can be found on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page#Data.*

We are proposing to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2025, as we continue to consider the public comments received in response to the FY 2024 rulemaking. We encourage interested parties to review the impacts and other information made available with the alternate test software (V41.A) and other additional files provided in connection with the FY 2024 IPPS/LTCH PPS proposed rule, as previously discussed, and we continue to welcome feedback for consideration for future rulemaking.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661), we continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of MS–DRG classification requests, consistent with our approach since FY 2021 when we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. Accordingly, in our analysis of the MS–DRG classification requests for FY 2025 that we received by October 20, 2023, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three-way split within the base MS-DRG	R2 > 3.0 for the two-way 1_23 split within the base MS-DRG	R2 > 3.0 for the two-way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2025 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2023 update of the FY 2023 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent 2 years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three-way split. In applying the criteria for a three-way split, a base MS–DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is then analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria fail, the next step is to determine if the criteria are satisfied for a two-way split. In applying the criteria for a two-way split, a base MS–DRG is initially subdivided into two subgroups: ''with MCC'' and ''without MCC'' (1_23) or ''with CC/MCC'' and ''without CC/MCC'' (12_3). Each subgroup is then analyzed in relation to the other using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits; however, we do not also evaluate the criteria for a three-way split.

2. Pre-MDC MS–DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies

We received a request to revise the title of Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies) in connection with an ICD–10–PCS procedure code request that was submitted via MEARIS™ by the December 1, 2023 deadline for consideration as an agenda topic to be discussed at the March 19–20, 2024 ICD–10 Coordination and Maintenance Committee meeting. The procedure code request involves the application of an autologous genetically engineered cell-based gene therapy, prademagene zamikeracel (PZ), that is indicated in the treatment of recessive dystrophic epidermolysis bullosa (RDEB), an extremely rare genetic disease of the skin that leads to large chronic wounds. The proposal was presented and discussed at the March 19–20, 2024 ICD–10 Coordination and Maintenance Committee meeting. We refer the reader to the CMS website at *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials. Public comments in response to the code proposal are due by April 19, 2024. The requestor suggested that if finalized, a new procedure code to identify the application of PZ should be assigned to Pre-MDC MS–DRG 018 and that the title for Pre-MDC MS–DRG 018 be revised to reflect ''Chimeric Antigen Receptor (CAR) T and Other Autologous Gene and Cell Therapies''.

Because the diagnosis and procedure code proposals that are presented at the March ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, as we have noted in prior rulemaking, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors

that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. Under this established process, the MS–DRG assignment for the upcoming fiscal year for any new diagnosis or procedure codes finalized after the March meeting would be reflected in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with the final rule for that fiscal year. Accordingly, the MS–DRG assignment for any new procedure codes describing PZ, if finalized following the March meeting, would be reflected in Table 6B.—New Procedure Codes associated with the final rule for FY 2025. As noted in prior rulemaking (87 FR 28135), the codes that are finalized after the March meeting are specifically identified with a footnote in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes that are made publicly available in association with the final rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* The public may provide feedback on these finalized assignments, which is then taken into consideration for the following fiscal year.

We do not agree with the request to revise the title for Pre-MDC MS–DRG 018 for FY 2025 as requested because the logic for Pre-MDC MS–DRG 018 is intended to include other immunotherapies and is not restricted to CAR T-cell and autologous gene and cell therapies. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), we finalized our proposal to revise the title of Pre-MDC MS–DRG 018 to include ''Other Immunotherapies'' to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies that would also be assigned to this MS–DRG, in addition to CAR T-cell therapies. We noted that the term ''Other Immunotherapies'' is intended to encompass the group of therapies that are currently available and being utilized today (for which codes have been created for reporting in response to industry requests or are being considered for implementation), and to enable appropriate MS–DRG assignment for any future therapies that may also fit into this category and are not specifically identified as a CAR T-cell product, that may become available (for example receive marketing authorization or a newly established procedure code in the ICD–10–PCS classification).

We also note, as discussed in prior rulemaking, that this category of therapies continues to evolve, and we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs. We appreciate the recommendations and suggestions for consideration we have received and will continue to examine these complex issues in connection with future rulemaking. We acknowledge that there may be distinctions to account for as we continue to gain more experience in the use of these therapies and have additional claims data to analyze. Therefore, we are not proposing to revise the title for Pre-MDC MS–DRG 018 to reflect ''Chimeric Antigen Receptor (CAR) T and Other Autologous Gene and Cell Therapies'' at this time and are proposing to maintain the existing title to Pre-MDC MS–DRG 018, ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' for FY 2025.

3. MDC 01 (Diseases and Disorders of the Nervous System)

a. Logic for MS–DRGs 023 Through 027

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661 through 58667), we discussed a request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) to MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC) or reassign all cases currently assigned to MS–DRG 023 that involve a craniectomy or a craniotomy with the insertion of device implant and create a new MS–DRG for these cases.

We stated the requestor acknowledged that the relatively low volume of cases that only involve the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain in the claims data was likely not sufficient to warrant the creation of a new MS–DRG. The requestor further stated given the limited options within the existing MS–DRG structure that fit from both a cost and clinical cohesiveness perspective, they believed that MS–DRG 021 was the most logical fit in terms of average costs and clinical coherence for reassignment even though, according to the requestor, the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain is technically more complex and involves a higher level of training, extreme precision and sophisticated technology than performing a craniectomy for hemorrhage.

We noted that while our data findings demonstrated the average costs are higher for the cases with a principal diagnosis of epilepsy with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain when compared to all cases in MS–DRG 023, these cases represented a small percentage of the total number of cases reported in this MS–DRG. We stated that while we appreciated the requestor's concerns regarding the differential in average costs for cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain when compared to all cases in their assigned MS–DRG, we believed additional time was needed to evaluate these cases as part of our ongoing examination of the case logic to the MS–DRGs for craniotomy and endovascular procedures, which are MS–DRG 023, MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively).

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48808 through 48820), in connection with our analysis of cases reporting laser interstitial thermal therapy (LITT) procedures performed on the brain or brain stem in MDC 01, we stated we have started to examine the logic for case assignment to MS–DRGs 023 through 027 to determine where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to those MS–DRGs. We stated that specifically, we were in the process of evaluating procedures that are performed using an open craniotomy (where it is necessary to surgically remove a portion of the skull) versus a percutaneous burr hole

(where a hole approximately the size of a pencil is drilled) to obtain access to the brain in the performance of a procedure. We stated we were also reviewing the indications for these procedures, for example, malignant neoplasms versus epilepsy to consider if there may be merit in considering restructuring the current MS–DRGs to better recognize the clinical distinctions of these patient populations in the MS–DRGs.

As part of this evaluation, as discussed in the FY 2024 IPPS/LTCH PPS final rule, we have begun to analyze the ICD–10 coded claims data to determine if the patients' diagnoses, the objective of the procedure performed, the specific anatomical site where the procedure is performed or the surgical approach used (for example, open, percutaneous, percutaneous endoscopic, among others) demonstrates a greater severity of illness and/or increased treatment difficulty as we consider restructuring MS–DRGs 023 through 027, including how to better align the clinical indications with the performance of specific intracranial procedures. We referred the reader to Tables 6P.2b through 6P.2f associated with the FY 2024 IPPS/LTCH PPS proposed rule (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for data analysis findings of cases assigned to MS–DRGs 023 through 027 from the September 2022 update of the FY 2022 MedPAR file as we continue to look for patterns of complexity and resource intensity.

In summary, we stated that while we agreed that neurostimulator cases can have average costs that are higher than the average costs of all cases in their respective MS–DRGs, in our analysis of this issue, it was difficult to detect patterns of complexity and resource intensity. Therefore, for the reasons discussed, we finalized our proposal to maintain the current assignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain for FY 2024.

In the FY 2024 IPPS/LTCH PPS final rule, we stated we continue to believe that additional time is needed to evaluate these cases as part of our ongoing examination of the case logic for MS–DRGs 023 through 027. As part of our ongoing, comprehensive analysis of the MS–DRGs under ICD–10, we stated we would continue to explore mechanisms to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. We stated that the data analysis as displayed in Tables 6P.2b through 6P.2f associated with the FY 2024 IPPS/LTCH PPS proposed rule was displayed to provide the public an opportunity to review our examination of the procedures by their approach (open versus percutaneous), clinical indications, and procedures that involve the insertion or implantation of a device and to reflect on what factors should be considered in the potential restructuring of these MS–DRGs. We welcomed further feedback on how CMS should define technical complexity, what factors should be considered in the analysis, and whether there are other data not included in Tables 6P.2b through 6P.2f that CMS should analyze. We also stated we are interested in receiving feedback on where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to these MS–DRGs.

In response to this discussion in the FY 2024 IPPS/LTCH PPS final rule, we received two comments by the October 20, 2023 deadline. A commenter recommended that CMS not use surgical approach (for example, open versus percutaneous) as a factor to reclassify MS–DRGs 023 through 027. The commenter stated whether the opening is created via a drill into the skull percutaneously or through a larger incision in the skull for a craniotomy, both approaches involve the risk of intracranial bleeding, infection, and brain swelling. The commenter further stated they do not support a consideration of the reassignment of the ICD–10–PCS procedure codes describing LITT, currently assigned to MS–DRGs 025 through 027, based on the diagnosis being treated. The commenter stated that the LITT procedure requires the same steps, time, and clinical resources when performed for brain cancer or epilepsy. In the requestor's view, differences in the disease causing the tumors or lesions do not affect the resources used for performing the procedure or the post-operative care for the patient. Lastly, the commenter stated they support the current structure of MS–DRGs 023 and 024 based on an acute complicated principal diagnosis, or chemotherapy implant, or epilepsy with neurostimulator. The commenter stated these diagnoses represent severe complex conditions that require immediate and urgent intervention.

Another commenter stated that the current logic for MS–DRGs 023 through 027 is sufficient and supports the clinical and resource similarities of the procedures reflected in these MS–DRGs. The commenter performed its own analysis and stated they found that realignment based on surgical approach or root operation could create significant new inequities. The commenter recommended that CMS maintain the current logic for MS–DRGs 025 through 027, as making changes could be disruptive to hospitals and create challenges for Medicare beneficiary access to life-saving technologies. The commenter stated they strongly believe that maintaining the current structure provides payment stability and integrity of these procedures over time.

CMS appreciates the comments submitted in response to the request for feedback in the FY 2024 IPPS/LTCH PPS final rule. As we continue analysis of the claims data with respect to MS–DRGs 023 through 027, we continue to seek public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs. As stated in prior rulemaking, we recognize the logic for MS–DRGs 023 through 027 has grown more complex over the years and believe there is opportunity for further refinement. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 023 through 027. Feedback and other suggestions may continue to be directed to MEARIS™, discussed in section II.C.1.b. of the preamble of this proposed rule at: *https://mearis.cms.gov/public/home.*

b. Intraoperative Radiation Therapy (IORT)

We received a request to add ICD–10–PCS procedure codes D0Y0CZZ (Intraoperative radiation therapy (IORT) of brain) and D0Y1CZZ (Intraoperative radiation therapy (IORT) of brain stem), to the Chemotherapy Implant logic list in MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator). According to the requestor, intraoperative radiation therapy (IORT) for the brain is always performed as part of the surgery to remove a brain tumor during the same operative episode. The requestor stated that once maximal safe tumor resection is achieved, the tumor cavity is examined for active egress of cerebrospinal fluid or bleeding. Next,

intraoperative measurements are made using neuro-navigation or intraoperative imaging such as magnetic resonance imaging (MRI) or computed tomography (CT) to ensure safe distance to organs or tissues at risk, aid in appropriate dose calculation, and selection of proper applicator size. The applicator is then implanted into the tumor cavity and the radiation dose is delivered. The requestor stated that delivery time can be up to 40 minutes and upon completion of the treatment, the source is removed, and the cavity is re-inspected for active egress of cerebrospinal fluid and bleeding.

The requestor stated that currently the ICD–10–PCS procedure codes for excision of a brain tumor, 00B00ZZ (Excision of brain, open approach) and 00B70ZZ (Excision of cerebral hemisphere, open approach) map to both sets of craniotomy MS–DRGs. Specifically, MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). However, the requestor also stated that the procedure codes describing IORT (D0Y0CZZ or D0Y1CZZ) are not listed in the GROUPER logic and do not affect MS–DRG assignment. Therefore, cases reporting a procedure code describing excision of a brain tumor (00B00ZZ or 00B70ZZ) with IORT currently map to MS–DRGs 025, 026, and 027. The requestor suggested that cases reporting a procedure code describing excision of a brain tumor (00B00ZZ or 00B70ZZ) with IORT (D0Y0CZZ or D0Y1CZZ) should map to MS–DRG 023 because of the higher costs associated with the addition of IORT to the excision of brain tumor surgery. According to the requestor, MS–DRG 023 includes complicated craniotomy cases involving the placement of radiological sources and chemotherapy implants. The requestor stated that because IORT involves a full course of radiation therapy delivered directly to the tumor bed via an applicator that is implanted into the tumor cavity during the same surgical session and is clinically similar to two other procedures listed in the Chemotherapy Implant logic list, it should also be included in the Chemotherapy Implant logic list. Specifically, the requestor stated procedure code 00H004Z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach) and procedure code 3E0Q305 (Introduction of other antineoplastic into cranial cavity and brain, percutaneous approach) also involve the delivery of either radiation or chemotherapy directly after tumor resection. According to the requestor, the resources involved in placing the delivery device are similar for all three procedures and the distinction is that the procedures described by codes 00H004Z and 3E0Q305 involve the insertion of devices that deliver radiation or chemotherapy over a period of time, whereas IORT delivers the entire dose of radiation during the operative session. As such, the requestor asserted that IORT is clinically aligned with the other procedures from a therapeutic and resource utilization perspective.

The requestor performed its own analysis using the FY 2022 MedPAR file that was made available in association with the FY 2024 IPPS/LTCH PPS final rule and stated it found fewer than 11 cases reporting IORT in MS–DRGs 025, 026, and 027, with the majority of those cases mapping to MS–DRG 025. According to the requestor, the volume of claims reporting IORT is anticipated to increase as appropriate use of the technology is adopted.

The requestor is correct that currently, the logic for case assignment to MS–DRG 023 includes a Chemotherapy Implant logic list and the procedure codes that identify IORT (D0Y0CZZ and D0Y1CZZ) are not listed in the GROUPER logic and do not affect MS–DRG assignment as the procedures are designated as non-O.R. procedures. The requestor is also correct that cases reporting a procedure code describing excision of a brain tumor (00B00ZZ or 00B70ZZ) with IORT currently map to MS–DRGs 025, 026, and 027. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic.

In review of this request, we analyzed claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRGs 023, 024, 025, 026, and 027 and for cases reporting excision of brain tumor and IORT. We identified claims reporting excision of brain tumor with procedure code 00B00ZZ or 00B70ZZ and identified claims reporting IORT with procedure code D0Y0CZZ or D0Y1CZZ. The findings from our analysis are shown in the following table. We note that there were no cases found to report IORT of brain (D0Y0CZZ) or brain stem (D0Y1CZZ) with excision of brain (00B00ZZ) or excision of cerebral hemisphere (00B70ZZ).

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MS-DRG		Number of cases	Average Length of Stay	Average Costs
23	All cases	11,439	10.3	$48,762
	Cases reporting excision of brain (00B00ZZ)	98	11.6	$61,938
	Cases reporting excision of cerebral hemisphere (00B70ZZ)	242	10.7	$58,498
	Cases reporting excision of brain (00B00ZZ) with IORT of brain (D0Y0CZZ)	0	0.0	$0
	Cases reporting excision of brain (00B00ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	All other cases	11,099	10.3	$48,433
24	All cases	4,641	5.1	$33,784
	Cases reporting excision of brain (00B00ZZ)	6	5.7	$32,308
	Cases reporting excision of cerebral hemisphere (00B70ZZ)	7	9.3	$34,707
	Cases reporting excision of brain (00B00ZZ) with IORT of brain (D0Y0CZZ)	0	0.0	$0
	Cases reporting excision of brain (00B00ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain stem (D0Y1CZZ)	0		$0
	All other cases	4,628	5.1	$33,785
25	All cases	21,118	8.8	$37,822
	Cases reporting excision of brain (00B00ZZ)	1,676	8.8	$38,410
	Cases reporting excision of cerebral hemisphere (00B70ZZ)	3,968	7.9	$33,904
	Cases reporting excision of brain (00B00ZZ) with IORT of brain (D0Y0CZZ)	0	0.0	$0
	Cases reporting excision of brain (00B00ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	All other cases	15,474	9.0	$38,763

26	All cases	5,882	4.5	$27,231
	Cases reporting excision of brain (00B00ZZ)	188	4.8	$26,093
	Cases reporting excision of cerebral hemisphere (00B70ZZ)	418	4.2	$23,867
	Cases reporting excision of brain (00B00ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of brain (00B00ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	All other cases	5,276	4.5	$27,538
27	All cases	7,232	2	$22,136
	Cases reporting excision of brain (00B00ZZ)	161	2.9	$20,695
	Cases reporting excision of cerebral hemisphere (00B70ZZ)	323	2.5	$21,039
	Cases reporting excision of brain (00B00ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of brain (00B00ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain (D0Y0CZZ)	0	0	$0
	Cases reporting excision of cerebral hemisphere (00B70ZZ) with IORT of brain stem (D0Y1CZZ)	0	0	$0
	All other cases	6,748	2.0	$22,223

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As the data show, there were no cases found to report the use of IORT in the performance of a brain tumor excision; therefore, we are unable to evaluate whether the use of IORT directly impacts resource utilization. For this reason, we are proposing to maintain the current structure of MS–DRGs 023, 024, 025, 026, and 027 for FY 2025. We will continue to monitor the claims data in consideration of any future modifications to the MS–DRGs for which IORT may be reported.

4. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Concomitant Left Atrial Appendage Closure and Cardiac Ablation

We received a request to create a new MS–DRG to better accommodate the costs of concomitant left atrial appendage closure and cardiac ablation for atrial fibrillation in MDC 05 (Diseases and Disorders of the Circulatory System). Atrial fibrillation (AF) is an irregular and often rapid heart rate that occurs when the two upper chambers of the heart experience chaotic electrical signals. AF presents as either paroxysmal (lasting <7 days), persistent (lasting >7 day, but less than 1 year), or long standing persistent (chronic) (lasting >1 year) based on time duration and can increase the risk for stroke, heart failure, and mortality. Management of AF has two primary goals: optimizing cardiac output through rhythm or rate control and decreasing the risk of cerebral and systemic thromboembolism. Among patients with AF, thrombus in the left atrial appendage (LAA) is a primary source for thromboembolism. Left Atrial Appendage Closure (LAAC) is a surgical or minimally invasive procedure to seal off the LAA to reduce the risk of embolic stroke.

According to the requestor, the manufacturer of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device, patients who are indicated for a LAAC device can also have symptomatic AF. For these patients, performing a cardiac ablation and LAAC procedure at the same time is ideal. Cardiac ablation is a procedure that works by burning or freezing tissue on the inside of the heart to disrupt faulty electrical signals causing the arrhythmia, which can help the heart maintain a normal heart rhythm. The requestor highlighted a recent study (Piccini et al. Left atrial appendage occlusion with the WATCHMAN™ FLX and concomitant catheter ablation procedures. Heart Rhythm Society Meeting 2023, May 19, 2023; New Orleans, LA.). According to the requestor, the results of this study indicate that when LAAC is performed concomitantly with cardiac ablation, the outcomes are comparable to patients who have undergone these procedures separately.

The requestor identified the following potential procedure code combination that would comprise a concomitant left atrial appendage closure and cardiac ablation procedure: ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach), that identifies the WATCHMAN™ device, in combination with 02583ZZ (Destruction of conduction mechanism, percutaneous approach). The requestor performed its own analysis of this procedure code combination and stated that it found the average costs of cases reporting concomitant left atrial appendage closure and cardiac ablation procedures were consistently higher compared to the average costs of other cases within their respective MS–DRG, which it asserted could limit beneficiary access to these procedures. The requestor asserted that improved Medicare payment for providers who perform these procedures concomitantly would help Medicare patients to gain better access to these lifesaving and quality-improving services and decrease the risk of future readmissions and the need for future procedures.

We reviewed this request and noted concerns regarding making proposed MS–DRG changes based on a specific, single technology (the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device) identified by only one unique procedure code versus considering proposed changes based on a group of related procedure codes that can be reported to describe the same type or class of technology, which is more consistent with the intent of the MS–DRGs. Therefore, in reviewing this request, we identified eight additional ICD–10–PCS procedure codes that describe LAAC procedures and included these codes in our analysis. The nine codes we identified are listed in the following table.

ICD-10-PCS Code	Description
02L70CK	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	Occlusion of left atrial appendage, open approach
02L73CK	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	Occlusion of left atrial Appendage with intraluminal device, percutaneous approach
02L73ZK	Occlusion of left atrial appendage, percutaneous approach
02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	Occlusion of left atrial appendage, percutaneous endoscopic approach

Similarly, as noted previously, the requestor identified code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) to describe cardiac ablation. In our review of the ICD–10–PCS classification, we identified 26 additional ICD–10–PCS codes that describe cardiac ablation that we also examined. The 27 codes we included in our analysis are listed in the following table.

ICD-10-PCS Code	Description
02540ZZ	Destruction of coronary vein, open approach
02543ZZ	Destruction of coronary vein, percutaneous approach
02544ZZ	Destruction of coronary vein, percutaneous endoscopic approach
02550ZZ	Destruction of atrial septum, open approach
02553ZZ	Destruction of atrial septum, percutaneous approach
02554ZZ	Destruction of atrial septum, percutaneous endoscopic approach
02560ZZ	Destruction of right atrium, open approach
02563ZZ	Destruction of right atrium, percutaneous approach
02564ZZ	Destruction of right atrium, percutaneous endoscopic approach
02570ZK	Destruction of left atrial appendage, open approach
02570ZZ	Destruction of left atrium, open approach
02573ZK	Destruction of left atrial appendage, percutaneous approach
02573ZZ	Destruction of left atrium, percutaneous approach
02574ZK	Destruction of left atrial appendage, percutaneous endoscopic approach
02574ZZ	Destruction of left atrium, percutaneous endoscopic approach
02580ZZ	Destruction of conduction mechanism, open approach
02583ZZ	Destruction of conduction mechanism, percutaneous approach
02584ZZ	Destruction of conduction mechanism, percutaneous endoscopic approach
02590ZZ	Destruction of chordae tendineae, open approach
02593ZZ	Destruction of chordae tendineae, percutaneous approach
02594ZZ	Destruction of chordae tendineae, percutaneous endoscopic approach
025S0ZZ	Destruction of right pulmonary vein, open approach
025S3ZZ	Destruction of right pulmonary vein, percutaneous approach
025S4ZZ	Destruction of right pulmonary vein, percutaneous endoscopic approach
025T0ZZ	Destruction of left pulmonary vein, open approach
025T3ZZ	Destruction of left pulmonary vein, percutaneous approach
025T4ZZ	Destruction of left pulmonary vein, percutaneous endoscopic approach

In the ICD–10 MS–DRGs Definitions Manual Version 41.1, for concomitant left atrial appendage closure and cardiac ablation procedures, the GROUPER logic assigns MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) depending on the presence of any additional MCC secondary diagnoses. We examined claims data from the September 2023 update of the FY 2023 MedPAR file for all cases in MS–DRGs 273 and 274 and compared the results to cases reporting procedure codes describing concomitant left atrial appendage closure and cardiac ablation. Our findings are shown in the following table.

MS-DRGs 273 and 274: All Cases and Cases Reporting Concomitant Left Atrial Appendage Closure and Cardiac Ablation				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
273	All cases	7,250	5.4	$35,197
	Cases with a procedure code LAAC and a procedure code for cardiac ablation	80	5.8	$70,447
274	All Cases	47,801	1.4	$29,209
	Cases with a procedure code LAAC and a procedure code for cardiac ablation	781	1.5	$66,277

As shown in the table, in MS–DRG 273, we identified a total of 7,250 cases with an average length of stay of 5.4 days and average costs of $35,197. Of those 7,250 cases, there were 80 cases reporting procedure codes describing concomitant left atrial appendage closure and cardiac ablation with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 273 ($70,447 compared to $35,197) and a slightly longer average length of stay (5.8 days compared to 5.4 days). In MS–DRG 274, we identified a total of 47,801 cases with an average length of stay of 1.4 days and average costs of $29,209. Of those 47,801 cases, there were 781 cases reporting procedure codes describing concomitant left atrial appendage closure and cardiac ablation, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 274 ($66,277 compared to $29,209) and a slightly longer average length of stay (1.5 days compared to 1.4 days).

We reviewed these data and note, clinically, the management of AF by performing concomitant left atrial appendage closure and cardiac ablation can improve symptoms, prevent stroke, and reduce the risk of bleeding compared with oral anticoagulants. The data analysis clearly shows that cases reporting concomitant left atrial appendage closure and cardiac ablation procedures have higher average costs and slightly longer lengths of stay compared to all the cases in their assigned MS–DRG. For these reasons, we are proposing to create a new MS–DRG for cases reporting a LAAC procedure and a cardiac ablation procedure.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the claims data from the September 2023 update of the FY 2023 MedPAR file. The following table illustrates our findings for all 1,723 cases reporting procedure codes describing concomitant left atrial appendage closure and cardiac ablation. We believe the resulting proposed MS–DRG assignment is more clinically homogeneous, coherent and better reflects hospital resource use.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Concomitant Left Atrial Appendage Closure and Cardiac Ablation	1,723	3.1	$54,629

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of this FY 2025 IPPS/LTCH PPS proposed rule. As shown in the table that follows, a three-way split of the proposed new MS–DRGs failed the criterion that there be at least 500 cases for each subgroup due to low volume. Specifically, for the ''with MCC'' split, there were only 268 cases in the subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	268	6.9	$60,667
With CC	772	2.9	$47,479
Without CC/MCC	683	1.7	$60,340

We then applied the criteria for a two-way split for the ''with CC/MCC'' and ''without CC/MCC'' subgroups and found that the criterion that there be at least a 20% difference in average cost between subgroups could not be met. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With CC/MCC	1,040	3.9	$50,877
Without CC/MCC	683	1.7	$60,340

We also applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that the criterion that there be at least 500 or more cases in each subgroup similarly could not be met. The criterion that there be at least a 20% difference in average costs between the subgroups also was not met. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	268	6.9	$60,667
Without MCC	1,455	2.3	$53,516

Therefore, for FY 2025, we are not proposing to subdivide the proposed new MS–DRG for cases reporting procedure codes describing concomitant left atrial appendage closure and cardiac ablation into severity levels.

In summary, for FY 2025, taking into consideration that it clinically requires greater resources to perform concomitant left atrial appendage closure and cardiac ablation procedures, we are proposing to create a new base MS–DRG for cases reporting a LAAC procedure and a cardiac ablation procedure in MDC 05. The proposed new MS–DRG is proposed new MS–DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation). We are also proposing to include the nine ICD–10–PCS procedure codes that describe LAAC procedures and 27 ICD–10–PCS procedure codes that describe cardiac ablation listed previously in the logic for assignment of cases reporting a LAAC procedure and a cardiac ablation procedure for the proposed new MS–DRG. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.15. of this proposed rule.

b. Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy)

The BAROSTIM™ system is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. The system consists of an implantable pulse generator (IPG) that is implanted subcutaneously in the upper chest below the clavicle, a stimulation lead that is sutured to either the right or left carotid sinus to activate the baroreceptors in the wall of the carotid artery, and a wireless programmer system that is used to non-invasively program and adjust BAROSTIM™ therapy via telemetry. The BAROSTIM™ system is indicated for the improvement of symptoms of heart failure in a subset of patients with symptomatic New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III) heart failure, with a low left ventricular ejection fraction, who also do not benefit from guideline directed pharmacologic therapy or qualify for Cardiac Resynchronization Therapy (CRT). The BAROSTIM™ system was approved for new technology add-on payments for FY 2021 (85 FR 58716 through 58717) and FY 2022 (86 FR 44974). The new technology add-on payment was subsequently discontinued effective FY 2023 (87 FR 48916).

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48837 through 48843), we discussed a request we received to reassign the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM™ system from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC respectively) to MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively). The requestor stated that the subset of patients that have an indication for the implantation of a BAROSTIM™ system also have indications for the implantation of Implantable Cardioverter Defibrillators (ICD), Cardiac Resynchronization Therapy Defibrillators (CRT–D) and/or Cardiac Contractility Modulation (CCM) devices, all of which also require the permanent implantation of a programmable, electrical pulse generator and at least one electrical lead. The requestor further stated that the average resource utilization required to implant the BAROSTIM™ system demonstrates a significant disparity compared to all procedures within MS–DRGs 252, 253, and 254.

In the FY 2023 IPPS/LTCH PPS final rule, we stated that the results of the claims analysis demonstrated we did not have sufficient claims data on which to base and evaluate any proposed changes to the current MS–DRG assignment. We also expressed concern in equating the implantation of a BAROSTIM™ system to the placement of ICD, CRT–D, and CCM devices as these devices all differ in terms of technical complexity and anatomical placement of the electrical lead(s). We noted there is no intravascular component or vascular puncture involved when implanting a BAROSTIM™ system. In contrast, the placement of ICD, CRT–D, and CCM devices generally involve a lead being affixed to the myocardium, being threaded through the coronary sinus or crossing a heart valve and are procedures that involve a greater level of complexity than affixing the stimulator lead to either the right or left carotid sinus when implanting a BAROSTIM™ system. We stated that we believed that as the number of cases reporting procedure codes describing the implantation of neuromodulation devices for heart failure increases, a better view of the associated costs and lengths of stay on average will be reflected in the data for purposes of assessing any reassignment of these cases. Therefore, after consideration of the public comments we received, and for the reasons stated earlier, we finalized our proposal to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device in MS–DRGs 252, 253, and 254 for FY 2023.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58712 through 58720), we discussed a request we received to add ICD–10–CM diagnosis code R57.0 (Cardiogenic shock) to the list of ''secondary diagnoses'' that grouped to MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction (AMI), Heart Failure (HF), or Shock with and without MCC, respectively). During our review of the issue, we noted that the results of our claims analysis showed that in procedures involving a cardiac defibrillator implant, the average costs and length of stay were generally similar without regard to the presence of diagnosis codes describing AMI, HF, or shock. We stated we believed that it may no longer be necessary to subdivide MS–DRGs 222, 223, 224, 225, 226, and 227 based on the diagnosis codes reported. After consideration of the public comments we received, and for the reasons stated in the rule, we finalized our proposal to delete MS–

DRGs 222, 223, 224, 225, 226, and 227. We also finalized our proposal to create new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC), new MS–DRG 276 (Cardiac Defibrillator Implant with MCC) and new MS–DRG 277 (Cardiac Defibrillator Implant without MCC) in MDC 05 for FY 2024.

For this FY 2025 IPPS/LTCH PPS proposed rule, we received a similar request to again review the MS–DRG assignment of the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM™ system. Specifically, the requestor recommended that CMS consider reassigning the ICD–10–PCS procedure codes that describe the implantation of the BAROSTIM™ system from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without MCC respectively) to MS–DRGs 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC), MS–DRG 276, and 277 (Cardiac Defibrillator Implant with MCC and without MCC respectively); or to other more clinically coherent MS–DRGs for implantable device procedures indicated for Class III heart failure patients. The requestor stated in their analysis the number of claims reporting procedure codes that describe the implantation of the BAROSTIM™ system has been consistently growing over the past few years. The requestor acknowledged that the implantation of the BAROSTIM™ system is predominantly performed in the outpatient setting but noted that a significant number of severely sick patients with multiple comorbidities (such as chronic kidney disease, end stage renal disease (ESRD), chronic obstructive pulmonary disease (COPD), and AF) are treated in an inpatient setting. The requestor stated in their experience, hospitals that have performed BAROSTIM™ procedures have stopped allowing patients to receive the device in the inpatient setting due to the high losses for each Medicare claim. The requestor asserted it is critically important to allow very sick and fragile patients access to the BAROSTIM™ procedure in an inpatient setting and stated these patients should not be denied access by hospitals due to the perceived gross underpayment of the current MS–DRG.

The requestor stated the BAROSTIM™ procedure is not clinically coherent with other procedures assigned to MS–DRGs 252, 253, and 254 (Other Vascular Procedures) as the majority of the ICD–10–PCS codes assigned to MS–DRGs 252, 253, and 254 describe procedures to identify, diagnose, clear and restructure veins and arteries, excluding those that require implantable devices. Furthermore, the requestor stated the costs of the implantable medical devices used for the BAROSTIM™ system (that is, the electrical pulse generator and electrical lead) alone far exceed the average costs of other cases assigned to MS–DRGs 252, 253, and 254.

The following ICD–10–PCS procedure codes uniquely identify the implantation of the BAROSTIM™ system: 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach) or 03HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach).

To analyze this request, we first examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRGs 252, 253, and 254 to identify cases reporting procedure codes describing the implantation of the BAROSTIM™ system with or without a procedure code describing the performance of a cardiac catheterization as MS–DRG 275 is defined by the performance of cardiac catheterization and a secondary diagnosis of MCC. Our findings are shown in the following table.

MS-DRGs 252-254: All Cases and Cases Reporting Procedures Describing the Implantation of a BAROSTIM™ System

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
252	All cases	18,964	8	$30,456
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	1	9	$110,928
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	12	7.8	$66,291
253	All cases	15,551	5.2	$22,870
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0	0	$0
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	7	4	$52,788
254	All cases	5,973	2.3	$15,778
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ with cardiac catheterization	0	0	$0
	Cases with diagnosis of heart failure with 0JH60MZ and 03HL3MZ or 03HK3MZ without cardiac catheterization	3	1.3	$29,740

As shown in the table, in MS–DRG 252, we identified a total of 18,964 cases with an average length of stay of 8 days and average costs of $30,456. Of those 18,964 cases, there was one case reporting procedure codes describing

the implantation of the BAROSTIM™ system with a procedure code describing the performance of a cardiac catheterization with costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 252 ($110,928 compared to $30,456) and a longer length of stay (9 days compared to 8 days). There were 12 cases reporting procedure codes describing the implantation of the BAROSTIM™ system without a procedure code describing the performance of a cardiac catheterization, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 252 ($66,291 compared to $30,456) and a slighter shorter average length of stay (7.8 days compared to 8 days). In MS–DRG 253, we identified a total of 15,551 cases with an average length of stay of 5.2 days and average costs of $22,870. Of those 15,551 cases, there were seven cases reporting procedure codes describing the implantation of the BAROSTIM™ system without a procedure code describing the performance of a cardiac catheterization, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 253 ($52,788 compared to $22,870) and a shorter average length of stay (4 days compared to 5.2 days). We found zero cases in MS–DRG 253 reporting procedure codes describing the implantation of a BAROSTIM™ system with a procedure code describing the performance of a cardiac catheterization. In MS–DRG 254, we identified a total of 5,973 cases with an average length of stay of 2.3 days and average costs of $15,778. Of those 5,973 cases, there were three cases reporting procedure codes describing the implantation of the BAROSTIM™ system without a procedure code describing the performance of a cardiac catheterization, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 254 ($29,740 compared to $15,778) and a shorter average length of stay (1.3 days compared to 2.3 days). We found zero cases in MS–DRG 254 reporting procedure codes describing the implantation of a BAROSTIM™ system with a procedure code describing the performance of a cardiac catheterization.

We then examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRGs 275, 276, and 277. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
275	3,358	10.3	$63,181
276	3,264	8.2	$54,993
277	3,840	4.2	$42,111

As the table shows, for MS–DRG 275, there were a total of 3,358 cases with an average length of stay of 10.3 days and average costs of $63,181. For MS–DRG 276, there were a total of 3,264 cases with an average length of stay of 8.2 days and average costs of $54,993. For MS–DRG 277, there were a total of 3,840 cases with an average length of stay of 4.2 days and average costs of $42,111.

In exploring mechanisms to address this request, we noted in total, there were only 23 cases reporting procedure codes describing the implantation of a BAROSTIM™ system in MS–DRGs 252, 253, and 254 (13, 7, and 3, respectively). We reviewed these data, and while we recognize that the average costs of the 23 cases reporting procedure codes describing the implantation of a BAROSTIM™ are greater when compared to the average costs of all cases in MS–DRGs 252, 253, and 254, the number of cases continues to be too small to warrant the creation of a new MS–DRG for these cases.

We further note, that of the 23 cases reporting procedure codes describing the implantation of a BAROSTIM™ system identified in MS–DRGs 252, 253, and 254, only one case reported the performance of cardiac catheterization. As discussed in the FY 2024 IPPS/LTCH PPS final rule, when reviewing the consumption of hospital resources for the cases reporting a cardiac defibrillator implant with cardiac catheterization during a hospital stay, the claims data clearly showed that the cases reporting secondary diagnoses designated as MCCs were more resource intensive as compared to other cases reporting cardiac defibrillator implant. Therefore, we finalized the creation of MS–DRG 275 for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC. Of the 23 cases reporting procedure codes describing the implantation of a BAROSTIM™ system, there was only one case reporting a procedure code describing the performance of cardiac catheterization and a secondary diagnosis designated as an MCC, and we note that there may have been other factors contributing to the higher costs of this one case. The results of the claims analysis demonstrate we do not have sufficient claims data on which to base and propose a change to the current MS–DRG assignment of cases reporting procedure codes describing the implantation of a BAROSTIM™ system from MS–DRGs 252, 253, and 254 to MS–DRG 275.

Further analysis of the claims data demonstrates that the 23 cases reporting procedure codes describing the implantation of a BAROSTIM™ system had an average length of stay of 5.8 days and average costs of $59,355, as compared to the 3,264 cases in MS–DRG 276 that had an average length of stay of 8.2 days and average costs of $54,993. While the cases reporting procedure codes describing the implantation of a BAROSTIM™ system had average costs that were $4,362 higher than the average costs of all cases in MS–DRG 276, as noted, there were only a total of 23 cases, and there may have been other factors contributing to the higher costs. We noted, however, reassigning all cases reporting procedure codes describing the implantation of a BAROSTIM™ system to MS–DRG 276, even if there is not a MCC present, the cases would receive higher payment and better account for the differences in resource utilization of these cases than in their respective MS–DRG.

We reviewed the clinical issues and the claims data, and while we continue to note that there is no intravascular component or vascular puncture involved when implanting a BAROSTIM™ system, and that the implantation of a BAROSTIM™ system is distinguishable from the placement of ICD, CRT–D, and CCM devices, as these devices all differ in terms of technical complexity and anatomical placement of the electrical lead(s), as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48837 through 48843), we agree that ICD, CRT–D, and CCM devices and the BAROSTIM™ system are clinically coherent in that they share an indication of heart failure, a major cause of morbidity and mortality in the United States, and that these cases demonstrate comparable resource utilization. Based on our review of the clinical issues and

the claims data, and to better account for the resources required, we are proposing to reassign the cases reporting procedure codes describing the implantation of a BAROSTIM™ system to MS–DRG 276, even if there is no MCC reported, to better reflect the clinical severity and resource use involved in these cases.

Therefore, for FY 2025, we are proposing to reassign all cases with one of the following ICD–10–PCS code combinations capturing cases reporting procedure codes describing the implantation of a BAROSTIM™ system, to MS–DRG 276, even if there is no MCC reported:

- 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach); and
- 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach).

We also are proposing to change the title of MS–DRG 276 from ''Cardiac Defibrillator Implant with MCC'' to ''Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator'' to reflect the proposed modifications to MS–DRG assignments. We note that discussion of the surgical hierarchy for this proposed modification is discussed in section II.C.15. of this proposed rule.

c. Endovascular Cardiac Valve Procedures

The human heart contains four major valves—the aortic, mitral, pulmonary, and tricuspid valves. These valves function to keep blood flowing through the heart. When conditions such as stenosis or insufficiency/regurgitation occur in one or more of these valves, valvular heart disease may result. Intervention options, including surgical aortic valve replacement or transcatheter aortic valve replacement can be performed to treat diseased or damaged aortic heart valves. Surgical aortic valve replacement (SAVR) is a traditional, open-chest surgery where an incision is made to access the heart. The damaged valve is replaced, and the chest is surgically closed. Since SAVR is a major surgery that involves an incision, recovery time tends to be longer. Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure that involves a catheter being inserted into an artery, without an incision for most cases, and then guided to the heart. The catheter delivers the new valve without the need for the chest or heart to be surgically opened. Since TAVR is a non-surgical procedure, it is generally associated with a much shorter recovery time.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49892 through 49893), we discussed a request we received to create a new MS–DRG that would only include the various types of cardiac valve replacements performed by an endovascular or transcatheter technique. We reviewed the claims data and stated the data analysis showed that cardiac valve replacements performed by an endovascular or transcatheter technique had a shorter average length of stay and higher average costs in comparison to all of the cases in their assigned MS–DRGs, which were MS–DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, and without CC/MCC, respectively). In the FY 2015 IPPS/LTCH PPS final rule we stated that patients receiving endovascular cardiac valve replacements were significantly different from those patients who undergo an open chest cardiac valve replacement and noted that patients receiving endovascular cardiac valve replacements are not eligible for open chest cardiac valve procedures because of a variety of health constraints, which we said highlights the fact that peri-operative complications and post-operative morbidity have significantly different profiles for open chest procedures compared with endovascular interventions. We further noted that separately grouping these endovascular valve replacement procedures provides greater clinical cohesion for this subset of high-risk patients. Therefore, we finalized our proposal to create MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement, with MCC and without MCC, respectively) for FY 2015.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42080 through 42089), we discussed a request we received to modify the MS–DRG assignment for transcatheter mitral valve repair (TMVR) with implant procedures. We reviewed the claims data and stated based on our data analysis, transcatheter cardiac valve repair procedures and transcatheter (endovascular) cardiac valve replacement procedures are more clinically coherent in that they describe endovascular cardiac valve interventions with implants, and were similar in terms of average length of stay and average costs to cases in MS–DRGs 266 and 267 when compared to other procedures in their current MS–DRG assignment. For the reasons described in the rule and after consideration of the public comments we received, we finalized our proposal to modify the structure of MS–DRGs 266 and 267 by reassigning the procedure codes that describe transcatheter cardiac valve repair (supplement) procedures, to revise the title of MS–DRG 266 from ''Endovascular Cardiac Valve Replacement with MCC'' to ''Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC'' and to revise the title of MS–DRG 267 from ''Endovascular Cardiac Valve Replacement without MCC'' to ''Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC'', to reflect the finalized restructuring.

For this FY 2025 IPPS/LTCH PPS proposed rule, we received a request to delete MS–DRGs 266 and 267 and to move the cases reporting transcatheter aortic valve replacement or repair (supplement) procedures currently assigned to those MS–DRGs into MS–DRGs 216, 217, 218, 219, 220, and 221. The requestor asserted that under the current IPPS payment methodology, TAVR procedures are not profitable to hospitals and when patients are clinically eligible for both a TAVR and SAVR procedures, factors beyond clinical appropriateness can drive treatment decisions. According to the requestor (the manufacturer of the SAPIEN™ family of transcatheter heart valves) sharing a single set of MS–DRGs would eliminate the current disincentives hospitals face and create financial neutrality between the two lifesaving treatment options. The requestor stated the current disincentives are increasingly problematic because they contribute to treatment disparities among certain racial, socioeconomic, and geographic groups.

The requestor noted that currently surgical cardiac valve replacement and supplement procedures, such as SAVR, are assigned to MS–DRGs 216, 217, 218, 219, 220, and 221, and endovascular cardiac valve replacement and supplement procedures, such as TAVR, are assigned to MS–DRGs 266 and 267. The requestor stated that both sets of MS–DRGs address valve disease and include valve repair or replacement procedures for any of the four heart valves. According to the requestor, while the sets of MS–DRGs involve clinically similar cases their payment rates differ which may be unintentionally influencing clinical decision-making by incentivizing hospitals to choose more invasive SAVR

procedures over less-invasive TAVR procedures.

As mentioned earlier, the requestor recommended that CMS delete MS–DRGs 266 and 267 and move the cases reporting transcatheter aortic valve replacement or repair (supplement) procedures currently assigned to those MS–DRGs into MS–DRGs 216, 217, 218, 219, 220, and 221. The requestor performed their own analysis and stated that their models of this suggested solution indicated the change would result in moderate differences in per case payments by case type and would not increase overall Medicare spending. The requestor noted that while their requested solution would potentially decrease payment to cases currently assigned to MS–DRGs 216, 217, 218, 219, 220, and 221, while at the same time increasing the payment to cases reporting endovascular cardiac valve replacement and supplement procedures, the results of their claim analysis demonstrated that the net difference in total payments across all cases would increase by approximately $6.5 million. The requestor stated that they anticipate that their proposed solution could increase Medicare patients' access to innovative endovascular cardiac valve procedures by establishing payment neutrality between SAVR and TAVR procedures.

We reviewed this request and note the requestor is correct that in Version 41.1 cases reporting procedure codes that describe endovascular cardiac valve replacement and supplement procedures, including TAVR, group to MS–DRGs 266 and 267. The requestor is also correct that cases reporting procedure codes that describe surgical cardiac valve replacement and supplement procedures, including SAVR, group to MS–DRGs 216, 217, 218, 219, 220, and 221. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 216, 217, 218, 219, 220, 221, 266 and 267.

To begin our analysis, we identified the ICD–10–PCS procedure codes that describe endovascular (transcatheter) cardiac valve replacement and supplement procedures and the ICD–10–PCS procedure codes that describe surgical cardiac valve replacement and supplement procedures. We also identified the ICD–10–PCS codes that describe cardiac catheterization, as MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) are defined by the performance of cardiac catheterization. We refer the reader to Table 6P.2a, Table 6P.2b, and Table 6P.2c, respectively, associated with this proposed rule (and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for the lists of the ICD–10–PCS procedure codes that we identified that describe endovascular cardiac valve replacement and supplement procedures, surgical cardiac valve replacement and supplement procedures, and cardiac catheterization procedures.

We then examined the claims data from the September 2023 update of the FY 2023 MedPAR file for all cases in MS–DRGs 216, 217, 218, 219, 220, and 221 and compared the results to cases reporting surgical cardiac valve replacement and supplement procedures in MS–DRG 216, 217, 218, 219, 220, and 221. The following table shows our findings:

MS-DRGs 216-221: All Cases and Cases Reporting Surgical Cardiac Valve Replacement and Supplement Procedures

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
216	All cases	5,033	13.9	$84,176
	Surgical cardiac valve replacement and supplement procedures	2,973	16.8	$87,497
217	All cases	1,635	7.2	$58,381
	Surgical cardiac valve replacement and supplement procedures	867	9.5	$56,829
218	All cases	275	3.4	$54,624
	Surgical cardiac valve replacement and supplement procedures	60	6.7	$45,096
219	All cases	12,458	10.5	$67,228
	Surgical cardiac valve replacement and supplement procedures	9,780	10.3	$64,954
220	All cases	9,829	6.3	$47,242
	Surgical cardiac valve replacement and supplement procedures	7,841	6.4	$46,245
221	All cases	1,242	3.8	$41,539
	Surgical cardiac valve replacement and supplement procedures	627	4.9	$39,081

As shown in the table, in MS–DRG 216, we identified a total of 5,033 cases with an average length of stay of 13.9 days and average costs of $84,176. Of those 5,033 cases, there were 2,973 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 216 ($87,497 compared to $84,176) and a longer average length of stay (16.8 days

compared to 13.9 days). In MS–DRG 217, we identified a total of 1,635 cases with an average length of stay of 7.2 days and average costs of $58,381. Of those 1,635 cases, there were 867 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 217 ($56,829 compared to $58,381) and a longer average length of stay (9.5 days compared to 7.2 days). In MS–DRG 218, we identified a total of 275 cases with an average length of stay of 3.4 days and average costs of $54,624. Of those 275 cases, there were 60 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 218 ($45,096 compared to $54,624) and a longer average length of stay (6.7 days compared to 3.4 days). In MS–DRG 219, we identified a total of 12,458 cases with an average length of stay of 10.5 days and average costs of $67,228. Of those 12,458 cases, there were 9,780 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 219 ($64,954 compared to $67,228), and a slightly shorter average length of stay (10.3 days compared to 10.5 days). In MS–DRG 220, we identified a total of 9,829 cases with an average length of stay of 6.3 days and average costs of $47,242. Of those 9,829 cases, there were 7,841 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 220 ($46,245 compared to $47,242) and a slightly longer average length of stay (6.4 days compared to 6.3 days). In MS–DRG 221, we identified a total of 1,242 cases with an average length of stay of 3.8 days and average costs of $41,539. Of those 1,242 cases, there were 627 cases reporting surgical cardiac valve replacement and supplement procedures, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 221 ($39,081 compared to $41,539) and a longer average length of stay (4.9 days compared to 3.8 days).

Next, we examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRGs 266 and 267. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
266	19,936	4.7	$54,188
267	36,665	1.5	$43,058

Because there is a two-way split within MS–DRGs 266 and 267 and there is a three-way split within MS–DRGs 216, 217, and 218, and MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively), we also analyzed the cases reporting a code describing an endovascular cardiac valve replacement and supplement procedure with a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC). We also analyzed the cases reporting a code describing an endovascular cardiac valve replacement and supplement procedure without a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a CC or an MCC.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
266	Endovascular cardiac valve replacement and supplement procedures with cardiac catheterization with MCC	5,443	7.9	$63,128
	Endovascular cardiac valve replacement and supplement procedures without cardiac catheterization with MCC	14,493	3.5	$50,831
267	Endovascular cardiac valve replacement and supplement procedures with cardiac catheterization with CC	4,761	2	$42,163
	Endovascular cardiac valve replacement and supplement procedures without cardiac catheterization with CC	22,996	1.5	$43,637
	Endovascular cardiac valve replacement and supplement procedures with cardiac catheterization without CC/MCC	1,386	1.3	$39,709
	Endovascular cardiac valve replacement and supplement procedures without cardiac catheterization without CC/MCC	7,522	1.2	$42,472

As shown in the table, the data analysis performed indicates that the 5,443 cases in MS–DRG 266 reporting endovascular cardiac valve replacement and supplement procedures with a procedure code describing the

performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC have an average length of stay that is shorter than the average length of stay (7.9 days versus 16.8 days) and lower average costs ($63,128 versus $87,497) when compared to the cases in MS–DRG 216 reporting surgical cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC. The 4,761 cases in MS–DRG 267 reporting endovascular cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC have an average length of stay that is shorter than the average length of stay (2 days versus 9.5 days) and lower average costs ($42,163 versus $56,829) when compared to the cases in MS–DRG 217 reporting surgical cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an CC. The 1,386 cases in MS–DRG 267 reporting endovascular cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC have an average length of stay that is shorter than the average length of stay (1.3 days versus 6.7 days) and lower average costs ($39,709 versus $45,096) when compared to the cases in MS–DRG 218 reporting surgical cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization, without a secondary diagnosis code designated as a CC or MCC.

The 14,493 cases in MS–DRG 266 reporting endovascular cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC have an average length of stay that is shorter than the average length of stay (3.5 days versus 10.3 days) and lower average costs ($50,831 versus $64,954) when compared to the cases in MS–DRG 219 reporting surgical cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC. The 22,996 cases in MS–DRG 267 reporting endovascular cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC have an average length of stay that is shorter than the average length of stay (1.5 days versus 6.4 days) and lower average costs ($43,637 versus $46,245) when compared to the cases in MS–DRG 220 reporting surgical cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an CC. The 7,522 cases in MS–DRG 267 reporting endovascular cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC have an average length of stay that is shorter than the average length of stay (1.2 days versus 4.9 days) and higher average costs ($42,472 versus $39,081) when compared to the cases in MS–DRG 221 reporting surgical cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization, without a secondary diagnosis code designated as a CC or MCC.

This data analysis shows the cases in MS–DRG 266 and 267 reporting endovascular cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a CC or a MCC have average costs lower than the average costs of cases reporting surgical cardiac valve replacement and supplement procedures with a procedure code describing the performance of a cardiac catheterization in the FY 2023 MedPAR file for MS–DRGs 216, 217, and 218 respectively, and the average lengths of stay are shorter. Similarly, the cases in MS–DRG 266 and 267 reporting endovascular cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a CC or a MCC generally have average costs lower than the average costs of cases reporting surgical cardiac valve replacement and supplement procedures without a procedure code describing the performance of a cardiac catheterization in the FY 2023 MedPAR file for MS–DRGs 219, 220, and 221 respectively, and the average lengths of stay are shorter.

For patients with an indication for cardiac valve replacement, clinical and anatomic factors must be considered when decision-making between procedures such as TAVR and SAVR. We note that SAVR is not a treatment option for patients with extreme surgical risk (that is, high probability of death or serious irreversible complication), severe atheromatous plaques of the ascending aorta such that aortic cross-clamping is not feasible, or with other conditions that would make operation through sternotomy or thoracotomy prohibitively hazardous. We agree that the endovascular or transcatheter technique presents a viable option for high-risk patients who are not candidates for the traditional open surgical approach, however we also note that TAVR is not indicated for every patient. TAVR is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections, or who have significant annuloplasty ring dehiscence.

We have concern with the assertion that clinicians perform more invasive surgical procedures, such as SAVR procedures, only to increase payment to their facility where minimally invasive TAVR procedures are also viable option. The choice of SAVR versus TAVR should not be based on potential facility payment. Instead, the decision on the procedural approach to be utilized should be based upon an individualized risk-benefit assessment that includes reviewing factors such as the patient's age, surgical risk, frailty, valve morphology, and presence of concomitant valve disease or coronary artery disease. As we have stated in prior rulemaking (83 FR 41201), it is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that involves increased costs. Conversely, it is not appropriate for facilities to recommend a specific type of therapy or treatment strictly because it may involve higher payment to the facility.

Also, we have concern with the requestor's assertion that sharing a single set of MS–DRGs could eliminate any perceived disincentives hospitals may face and create financial neutrality between the two lifesaving treatment options. Data analysis shows that cases reporting surgical cardiac valve

replacement and supplement procedures have higher costs and longer lengths of stay. If clinical decision-making is being driven by financial motivations, as suggested by the requestor, in circumstances where the decision on which approach is best (for example, TAVR or SAVR) is left to the providers' discretion, it is unclear how reducing payment for surgical cardiac valve replacement and supplement procedures would eliminate possible disincentives, or not have the opposite effect, and instead incentivize endovascular cardiac valve replacement and supplement procedures.

The MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources and are not intended to be utilized as a tool to incentivize the performance of certain procedures. When performed, surgical cardiac valve replacement and supplement procedures are clinically different from endovascular cardiac valve replacement and supplement procedures in terms of technical complexity and hospital resource use. In the FY 2015 IPPS/LTCH PPS final rule, we stated that separately grouping endovascular valve replacement procedures provides greater clinical cohesion for this subset of high-risk patients. Our claims analysis for this FY 2025 IPPS/LTCH PPS proposed rule demonstrates that this continues to be substantiated by the difference in average costs and average lengths of stay demonstrated by the two cohorts. We continue to believe that endovascular cardiac valve replacement and supplement procedures are clinically coherent in their currently assigned MS–DRGs. Therefore, we are proposing to maintain the structure of MS–DRGs 266 and 267 for FY 2025.

d. MS–DRG Logic for MS–DRG 215

We received a request to review the GROUPER logic for MS–DRG 215 (Other Heart Assist System Implant) in MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated that when the procedure code describing the revision of malfunctioning devices within the heart via an open approach is assigned, the encounter groups to MS–DRG 215. The requestor stated that, in their observation, ICD–10–PCS code 02WA0JZ (Revision of synthetic substitute in heart, open approach) can only be assigned if a more specific anatomical site is not documented in the operative note. The requestor further stated they interpreted this to mean that an ICD–10–PCS procedure code describing the open revision of a synthetic substitute in the heart can only apply to the ventricular wall or left atrial appendage and excludes the atrial or ventricular septum or any valve to qualify for MS–DRG 215 and recommended that CMS consider the expansion of the open revision of heart structures to include the atrial or ventricular septum and heart valves.

To begin our analysis, we reviewed the GROUPER logic. The requestor is correct that ICD–10–PCS procedure code 02WA0JZ is currently one of the listed procedure codes in the GROUPER logic for MS–DRG 215. While the requestor stated that when procedures codes describing the revisions of malfunctioning devices within the heart via an open approach are assigned, the encounter groups to MS–DRG 215, we wish to clarify that the revision codes listed in the GROUPER logic for MS–DRG 215 specifically describe procedures to correct, to the extent possible, a portion of a malfunctioning heart assist device or the position of a displaced heart assist device. Further, it is unclear what is meant by the requestor's statement that ICD–10–PCS code 02WA0JZ can only be assigned if more specific anatomical site is not documented in the operative note, as ICD–10–PCS code 02WA0JZ is used to describe the open revision of artificial heart systems. Total artificial hearts are pulsating bi-ventricular devices that are implanted into the chest to replace a patient's left and right ventricles and can provide a bridge to heart transplantation for patients who have no other reasonable medical or surgical treatment options. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software)* for complete documentation of the GROUPER logic for MS–DRG 215. We encourage the requestor and any providers that have cases involving heart assist devices for which they need ICD–10 coding assistance and clarification on the usage of the codes, to submit their questions to the American Hospital Association's Central Office on ICD–10 at *https://www.codingclinicadvisor.com/*.

As previously noted, the requestor recommended that we consider expansion of the open revision of heart structures to include the atrial or ventricular septum and heart valves. The requestor did not provide a specific list of procedure codes involving the open revision of heart structures. While not explicitly stated, we understood this request to be for our consideration of the reassignment of the procedure codes describing the open revision of devices in the heart valves, atrial septum, or ventricular septum to MS–DRG 215, therefore, we reviewed the ICD–10–PCS classification and identified the following 18 procedure codes. These 18 codes are all assigned to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) in MDC 05 in Version 41.1.

ICD-10-PCS Code	Description
02W50JZ	Revision of synthetic substitute in atrial septum, open approach
02WF07Z	Revision of autologous tissue substitute in aortic valve, open approach
02WF08Z	Revision of zooplastic tissue in aortic valve, open approach
02WF0JZ	Revision of synthetic substitute in aortic valve, open approach
02WF0KZ	Revision of nonautologous tissue substitute in aortic valve, open approach
02WG07Z	Revision of autologous tissue substitute in mitral valve, open approach
02WG08Z	Revision of zooplastic tissue in mitral valve, open approach
02WG0JZ	Revision of synthetic substitute in mitral valve, open approach
02WG0KZ	Revision of nonautologous tissue substitute in mitral valve, open approach
02WH07Z	Revision of autologous tissue substitute in pulmonary valve, open approach
02WH08Z	Revision of zooplastic tissue in pulmonary valve, open approach
02WH0JZ	Revision of synthetic substitute in pulmonary valve, open approach
02WH0KZ	Revision of nonautologous tissue substitute in pulmonary valve, open approach
02WJ07Z	Revision of autologous tissue substitute in tricuspid valve, open approach
02WJ08Z	Revision of zooplastic tissue in tricuspid valve, open approach
02WJ0JZ	Revision of synthetic substitute in tricuspid valve, open approach
02WJ0KZ	Revision of nonautologous tissue substitute in tricuspid valve, open approach
02WM0JZ	Revision of synthetic substitute in ventricular septum, open approach

Next, we examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRG 228 and 229 to identify cases reporting one of the 18 codes listed previously that describe the open revision of devices in the heart valves, atrial septum, or ventricular septum. Our findings are shown in the following table:

MS-DRGs 228 – 229: All Cases and Cases Reporting Open Revision of Devices in the Heart Valves, Atrial Septum, or Ventricular Septum

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
228	All cases	4,391	8.7	$44,565
	Cases with a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum	12	15.7	$51,549
229	All Cases	5,712	3.3	$28,987
	Cases with a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum	1	1	$11,322

As shown in the table, in MS–DRG 228, we identified a total of 4,391 cases with an average length of stay of 8.7 days and average costs of $44,565. Of those 4,391 cases, there were 12 cases reporting a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 228 ($51,549 compared to $44,565) and a longer average length of stay (15.7 days compared to 8.7 days). In MS–DRG 229, we identified a total of 5,712 cases with an average length of stay of 3.3 days and average costs of $28,987. Of those 5,712 cases, there was one case reporting a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum with costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 229 ($11,322 compared to $28,987) and a shorter length of stay (1 day compared to 3.3 days).

We then examined claims data from the September 2023 update of the FY 2023 MedPAR for MS–DRG 215. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
215	3,668	9.2	$91,021

Our analysis indicates that the cases assigned to MS–DRG 215 have much higher average costs than the cases reporting a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum currently assigned to MS–DRGs 228 and 229. Instead, the average costs and average length of stay for case reporting a procedure code describing the open revision of devices in the heart valves, atrial septum, or ventricular septum appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 228 and 229, where they are currently assigned.

In addition, based on our review of the clinical considerations, we do not believe the procedure codes describing the open revision of devices in the heart valves, atrial septum, or ventricular septum are clinically coherent with the procedure codes currently assigned to MS–DRG 215. Heart assist devices, such as ventricular assist devices and artificial heart systems, provide circulatory support by taking over most of the workload of the left ventricle. Blood enters the pump through an

inflow conduit connected to the left ventricle and is ejected through an outflow conduit into the body's arterial system. Heart assist devices can provide temporary left, right, or biventricular support for patients whose hearts have failed and can also be used as a bridge for patients who are awaiting a heart transplant. Devices placed in the heart valves, atrial septum, or ventricular septum do not serve the same purpose as heart assist devices and we do not believe the procedure codes describing the revision of these devices should be assigned to MS–DRG 215. Further, the various indications for devices placed in the heart valves, atrial septum or ventricular septum are not aligned with the indications for heart assist devices. We believe that patients with indications for heart assist devices tend to be more severely ill and these inpatient admissions are associated with greater resource utilization. Therefore, for the reasons stated previously, we are proposing to maintain the GROUPER logic for MS–DRG 215 for FY 2025.

5. MDC 06 (Diseases and Disorders of the Digestive System): Excision of Intestinal Body Parts

We identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs regarding the assignment of eight ICD–10–PCS codes that describe the excision of intestinal body parts by open, percutaneous, or percutaneous endoscopic approach. Under the Version 32 ICD–9 based MS–DRGs, ICD–9–CM procedure code 45.33 (Local excision of lesion or tissue of small intestine, except duodenum) was designated as an O.R. procedure and was assigned to MDC 06 (Diseases and Disorders of the Digestive System) in MS–DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively).

There are eight ICD–10–PCS code translations that provide more detailed and specific information for ICD–9–CM code 45.33 that also currently group to MS–DRGs 347, 348, and 349 in the ICD–10 MS–DRGs Version 41.1. These eight procedure codes are shown in the following table:

ICD-10-PCS Code	Description
0DB83ZZ	Excision of small intestine, percutaneous approach
0DBA3ZZ	Excision of jejunum, percutaneous approach
0DBA4ZZ	Excision of jejunum, percutaneous endoscopic approach
0DBB3ZZ	Excision of ileum, percutaneous approach
0DBB4ZZ	Excision of ileum, percutaneous endoscopic approach
0DBC0ZZ	Excision of ileocecal valve, open approach
0DBC3ZZ	Excision of ileocecal valve, percutaneous approach
0DBC4ZZ	Excision of ileocecal valve, percutaneous endoscopic approach

We noted during our review of this issue that under ICD–9–CM, procedure code 45.33 did not differentiate the specific type of approach used to perform the procedure. This is in contrast to the eight comparable ICD–10–PCS code translations listed in the previous table that do differentiate among various approaches (open, percutaneous, and percutaneous endoscopic). We also noted that there are four additional ICD–10–PCS code translations that provide more detailed and specific information for ICD–9–CM code 45.33, however these four codes currently group to MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively), and not MS–DRGs 347, 348, and 349, in the ICD–10 MS–DRGs Version 41.1. These four procedure codes are shown in the following table:

ICD-10-PCS Code	Description
0DB80ZZ	Excision of small intestine, open approach
0DB84ZZ	Excision of small intestine, percutaneous endoscopic approach
0DBA0ZZ	Excision of jejunum, open approach
0DBB0ZZ	Excision of ileum, open approach

We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software)* for complete documentation of the GROUPER logic for MS–DRGs 329, 330, 331, 347, 348, and 349.

Next, we examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRG 347, 348, and 349 to identify cases reporting one of the eight codes listed previously that describe excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach. Our findings are shown in the following table:

MS-DRGs 347 – 349: All Cases and Cases Reporting One of Eight Procedure Codes Describing Excision of an Intestinal Body Part by Open, Percutaneous, or Percutaneous Endoscopic Approach				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
347	All cases	752	7.6	$21,462
	Cases with 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, or 0DBC4ZZ	66	8.5	$27,081
348	All cases	1,580	4.2	$12,020
	Cases with 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, or 0DBC4ZZ	192	4.9	$17,063
349	All Cases	644	2.2	$9,095
	Cases with 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, or 0DBC4ZZ	117	3	$14,612

As shown in the table, in MS–DRG 347, we identified a total of 752 cases with an average length of stay of 7.6 days and average costs of $21,462. Of those 752 cases, there were 66 cases reporting one of eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 347 ($27,081 compared to $21,462) and a longer average length of stay (8.5 days compared to 7.6 days). In MS–DRG 348, we identified a total of 1,580 cases with an average length of stay of 4.2 days and average costs of $12,020. Of those 1,580 cases, there were 192 cases reporting one of eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 348 ($17,063 compared to $12,020) and a longer average length of stay (4.9 days compared to 4.2 days). In MS–DRG 349, we identified a total of 644 cases with an average length of stay of 2.2 days and average costs of $9,095. Of those 644 cases, there were 117 cases reporting one of eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 349 ($14,612 compared to $9,095), and a longer average length of stay (3 days compared to 2.2 days).

We then examined claims data from the September 2023 update of the FY 2023 MedPAR for MS–DRGs 329, 330, and 331. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
329	28,706	12.5	$38,468
330	37,642	6.3	$20,852
331	18,004	3.3	$14,796

While the average costs for all cases in MS–DRGs 329, 330, and 331 are higher than the average costs of the cases reporting one of eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach, the data suggest that overall, cases reporting one of eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach may be more appropriately aligned with the average costs of the cases in MS–DRGs 329, 330, and 331 in comparison to MS–DRGs 347, 348, and 349, even though the average lengths of stay are shorter.

We reviewed this grouping issue, and our analysis indicates that the eight procedure codes describing the excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach were initially assigned to the list of procedures in the GROUPER logic for MS–DRGs 347, 348, and 349 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs. We also note that procedure codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, and 0DBC4ZZ do not describe procedures on a stoma, which is an artificial opening on the abdomen that can be connected to either the digestive or urinary system to allow waste to be diverted out of the body, or the anus. We support the reassignment of codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, and 0DBC4ZZ for clinical coherence and believe these eight procedure codes should be appropriately grouped along with the four other procedure codes that describe excision of intestinal body parts by an open, or percutaneous endoscopic approach currently assigned to MS–DRGs 329, 330, and 331.

Accordingly, because the procedures described by the eight procedure codes that describe excision of intestinal body parts by an open, percutaneous, or percutaneous endoscopic approach are not clinically consistent with procedures on the anus or stoma, and it is clinically appropriate to reassign these procedures to be consistent with the four other procedure codes that describe excision of intestinal body parts by an open, or percutaneous endoscopic approach in MS–DRGs 329, 330, and 331, we are proposing the reassignment of procedure codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, and 0DBC4ZZ from MS–DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06, effective FY 2025.

6. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. MS–DRG Logic for MS–DRGs 456, 457, and 458

We identified an inconsistency in the GROUPER logic for MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) related to ICD–10–CM diagnosis codes describing deforming dorsopathies. The logic for case assignment to MS–DRGs 456, 457, and 458 as displayed in the ICD–10 MS–DRG Definitions Manual Version 41.1 (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) is comprised of four logic lists. The first logic list is entitled ''Spinal Fusion Except Cervical'' and is defined by a list of procedure codes designated as O.R. procedures that describe spinal fusion procedures of the thoracic, thoracolumbar, lumbar, lumbosacral, sacrococcygeal, coccygeal, and sacroiliac joint. The second logic list is entitled ''Spinal Curvature/Malignancy/Infection'' and is defined by a list of diagnosis codes describing spinal curvature, spinal malignancy, and spinal infection that are used to define the logic for case assignment when any one of the listed diagnosis codes is reported as the principal diagnosis. The third logic list is entitled ''OR Secondary Diagnosis'' and is defined by a list of diagnosis codes describing curvature of the spine that are used to define the logic for case assignment when any one of the listed codes is reported as a secondary diagnosis. The fourth logic list is entitled ''Extensive Fusions'' and is defined by a list of procedure codes designated as O.R. procedures that describe extensive spinal fusion procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1, (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 456, 457, and 458.

In the second logic list entitled ''Spinal Curvature/Malignancy/Infection'' there are a subset of six diagnosis codes describing other specified deforming dorsopathies as shown in the following table.

ICD-10-CM Code	Description
M43.8X4	Other specified deforming dorsopathies, thoracic region
M43.8X5	Other specified deforming dorsopathies, thoracolumbar region
M43.8X6	Other specified deforming dorsopathies, lumbar region
M43.8X7	Other specified deforming dorsopathies, lumbosacral region
M43.8X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M43.8X9	Other specified deforming dorsopathies, site unspecified

In the third logic list entitled ''OR Secondary Diagnosis'' there are currently 14 diagnosis codes listed, one of which is diagnosis code M43.8X9 (Other specified deforming dorsopathies, site unspecified) as shown in the following table.

OR Secondary Diagnosis Codes	
ICD-10-CM Code	**Description**
M40.10	Other secondary kyphosis, site unspecified
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M41.40	Neuromuscular scoliosis, site unspecified
M41.44	Neuromuscular scoliosis, thoracic region
M41.45	Neuromuscular scoliosis, thoracolumbar region
M41.46	Neuromuscular scoliosis, lumbar region
M41.47	Neuromuscular scoliosis, lumbosacral region
M41.50	Other secondary scoliosis, site unspecified
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
M43.8X9	Other specified deforming dorsopathies, site unspecified

We recognized that the five diagnosis codes describing deforming dorsopathies of specific anatomic sites that are listed in the second logic list entitled ''Spinal Curvature/Malignancy/Infection'' are not listed in the third logic list entitled ''OR Secondary Diagnosis'', rather, only diagnosis code M43.8X9 (Other specified deforming dorsopathies, site unspecified) appears in both logic lists. Therefore, we considered if it was clinically appropriate to add the five diagnosis codes describing deforming dorsopathies of specific anatomic sites that are listed in the second logic list entitled ''Spinal Curvature/Malignancy/Infection'' to the third logic list entitled ''OR Secondary Diagnosis''.

A deforming dorsopathy is characterized by abnormal bending or flexion in the vertebral column. All spinal deformities involve problems with curve or rotation of the spine, regardless of site specificity. We believe the five diagnosis codes describing deforming dorsopathies of specific anatomic sites to be clinically aligned with the diagnosis codes currently

included in the ''OR Secondary Diagnosis'' logic list. Therefore, for clinical consistency we are proposing to add diagnosis codes M43.8X4, M43.8X5, M43.8X6, M43.8X7, and M43.8X8 to the ''OR Secondary Diagnosis'' logic list for MS–DRGs 456, 457, and 458, effective October 1, 2024 for FY 2025.

b. Interbody Spinal Fusion Procedures

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26726 through 26729) and final rule (88 FR 58731 through 58735, as corrected in the FY 2024 final rule correction notice at 88 FR 77211), we discussed a request we received to reassign cases reporting spinal fusion procedures using an aprevo™ customized interbody fusion device from the lower severity MS–DRG 455 (Combined Anterior and Posterior Spinal Fusion without CC/MCC) to the higher severity MS–DRG 453 (Combined Anterior and Posterior Spinal Fusion with MCC), from the lower severity MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC) to the higher severity level MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC) when a diagnosis of malalignment is reported, and from MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively) to MS–DRG 456. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software)* for complete documentation of the GROUPER logic.

We also noted that the aprevo™ Intervertebral Body Fusion Device technology was approved for new technology add-on payments for FY 2022 (86 FR 45127 through 45133). We further noted that, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49468 through 49469), CMS finalized the continuation of the new technology add-on payments for this technology for FY 2023. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58802), we finalized the continuation of new technology add-on payments for the transforaminal lumbar interbody fusion (TLIF) indication for aprevo™ for FY 2024, and the discontinuation of the new technology add-on payments for the anterior lumbar interbody fusion (ALIF) and lateral lumbar interbody fusion (LLIF) indications for FY 2024. We refer the reader to section II.E. for discussion of the FY 2025 status of technologies receiving new technology add-on payments for FY 2024, including the status for the aprevo™ technology.

As also discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26726 through 26729) and final rule (88 FR 58731 through 58735), effective October 1, 2021 (FY 2022), we implemented 12 new ICD–10–PCS procedure codes to identify and describe spinal fusion procedures using the aprevo™ customized interbody fusion device. In the proposed rule we noted that the manufacturer expressed concerns that there may be unintentional miscoded claims from providers with whom they do not have an explicit relationship and that following the submission of the request for the FY 2024 MS–DRG classification change for cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device, it submitted a code proposal requesting a revision to the title of the procedure codes that were finalized effective FY 2022. As discussed in the FY 2024 IPPS/LTCH PPS final rule, a proposal to revise the code title for the procedure codes that identify and describe spinal fusion procedures using the aprevo™ customized interbody fusion device was presented and discussed as an Addenda item at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting and subsequently finalized.

The code title changes for the 12 ICD–10–PCS procedure codes to identify and describe spinal fusion procedures using the aprevo™ customized interbody fusion device were reflected in the FY 2024 ICD–10–PCS Code Update files available via the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-pcs,* as well as in Table 6F.—Revised Procedure Code Titles—FY 2024 associated with the FY 2024 IPPS/LTCH PPS final rule and available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* We note that only the code titles were revised and the code numbers themselves did not change.

Accordingly, effective with discharges on and after October 1, 2023 (FY 2024), the 12 ICD–10–PCS procedure codes to identify and describe spinal fusion procedures using the aprevo™ customized interbody fusion device with their revised code titles are as follows:

ICD-10-PCS Code	Description
XRGA0R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGA3R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGA4R7	Fusion of thoracolumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGB0R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGB3R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGB4R7	Fusion of lumbar vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGD0R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 7
XRGD3R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 7
XRGD4R7	Fusion of lumbosacral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 7

As discussed in the FY 2024 proposed and final rules, as part of our analysis of the manufacturer's request to reassign cases involving the aprevo™ device, we presented findings from our analysis of claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 and cases reporting any one of the 12 original procedure codes describing utilization of an aprevo™ customized interbody spinal fusion device. We stated that while we agreed that the findings from our analysis appeared to indicate that cases reporting the performance of a procedure using an aprevo™ customized interbody spinal fusion device reflected a higher consumption of resources, due to the concerns expressed with respect to suspected inaccuracies of the coding and therefore, reliability of the claims data, we would continue to monitor the claims data for resolution of the potential coding issues identified by the requestor (the manufacturer). We stated that we continued to believe additional review of claims data was warranted and would be informative as we continued to consider cases involving this technology for future rulemaking. Specifically, we stated we believed it would be premature to propose any MS–DRG modifications for spinal fusion procedures using an aprevo™ customized interbody spinal fusion device for FY 2024 and finalized our proposal to maintain the structure of MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460, without modification, for FY 2024 (88 FR 58734 through 58735). As discussed further in the FY 2024 final rule correction, in response to the manufacturer's comment expressing concern about the reliability of the Medicare claims data in the MedPAR file used for purposes of CMS's claims data analysis, as compared to the manufacturer's analysis of its own customer claims data, we stated that in order for us to consider using non-MedPAR data, the non-MedPAR data must be independently validated, meaning when an entity submits non-MedPAR data, we must be able to independently review the medical records and verify that a particular procedure was performed for each of the cases that purportedly involved the procedure. We noted that, in this particular circumstance, where external data for cases reporting the use of an aprevo™ spinal fusion device was provided, we did not have access to the medical records to conduct an independent review; therefore, we were not able to validate or confirm the non-MedPAR data submitted by the commenter for consideration in FY 2024. However, we also noted that our work in this area was ongoing, and we would continue to examine the data and consider these issues as we develop potential future rulemaking proposals. We refer readers to the FY 2024 IPPS/LTCH PPS correction notice (88 FR 77211) for further discussion.

In advance of this FY 2025 IPPS/LTCH PPS proposed rule, the manufacturer provided us with a list of the providers with which it indicated it has an explicit relationship to assist in our ongoing review of its request for reassignment of cases reporting spinal fusion procedures using an aprevo™ interbody fusion device from the lower severity spinal fusion MS–DRGs to the higher severity level spinal fusion MS–DRGs.

To continue our analysis of cases reporting spinal fusion procedures using an aprevo™ customized interbody fusion device, we first analyzed claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460, and cases reporting any one of the previously listed procedure codes describing the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device.[3] Our findings are shown in the following tables.

[3] As noted earlier in the discussion, the code titles were updated but the code numbers themselves did not change.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 453 All cases	4,066	9.5	$80,420
MS-DRG 453 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	26	9.8	$99,162
MS-DRG 454 All cases	20,425	4.3	$54,983
MS-DRG 454 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	129	4.9	$71,527
MS-DRG 455 All cases	17,000	2.6	$41,015
MS-DRG 455 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	87	2.6	$54,922
MS-DRG 456 All cases	1,475	12.6	$76,060
MS-DRG 456 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	2	8.5	$69,009
MS-DRG 457 All cases	3,730	6.1	$52,179
MS-DRG 457 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	11	5	$47,221
MS-DRG 458 All cases	1,260	3.1	$39,260
MS-DRG 458 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	6	3	$53,140
MS-DRG 459 All cases	3,152	9.6	$53,192
MS-DRG 459 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	1	22	$288,499
MS-DRG 460 All cases	28,698	3.4	$32,586
MS-DRG 460 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	64	2.4	$53,513

Summary Data for MS-DRGs 453, 454 and 455			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRGs 453, 454, and 455 All cases	41,491	4.1	$51,753
MS-DRGs 453, 454, and 455 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	242	4.6	$68,526

Summary Data for MS-DRGs 456, 457 and 458			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRGs 456, 457, and 458 All cases	6,465	7.0	$55,110
MS-DRGs 456, 457, and 458 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	19	4.7	$51,384

Summary Data for MS-DRGs 459 and 460			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRGs 459 and 460 All cases	31,850	4.0	$34,625
MS-DRGs 459 and 460 Cases reporting spinal fusion using a custom-made anatomically designed interbody fusion device	65	2.7	$57,128

We identified the majority of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 453, 454, and 455 with a total of 242 cases (26 + 129 + 87 = 242) with an average length of stay of 4.6 days and average costs of $68,526. The 26 cases found in MS–DRG 453 appear to have a comparable average length of stay (9.8 days versus 9.5 days) and higher average costs ($99,162 versus $80,420) compared to all the cases in MS–DRG 453, with a difference in average costs of $18,742 for the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device. The 129 cases found in MS–DRG 454 appear to have a comparable average length of stay (4.9 days versus 4.3 days) and higher average costs ($71,527 versus $54,983) compared to all the cases in MS–DRG 454, with a difference in average costs of $16,544 for the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device. The 87 cases found in MS–DRG 455 have an identical average length of stay of 2.6 days in comparison to all the cases in MS–DRG 455, however, the difference in average costs is $13,907 ($54,922 − $41,015 = $13,907) for the cases reporting the performance of a spinal fusion procedure using an

aprevo™ custom-made anatomically designed interbody fusion device.

For MS–DRGs 456, 457, and 458, we found a total of 19 cases (2 + 11 + 6 = 19) reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device with an average length of stay of 4.7 days and average costs of $51,384. The 2 cases found in MS–DRG 456 have a shorter average length of stay (8.5 days versus 12.6 days) and lower average costs ($69,009 versus $76,060) compared to all the cases in MS–DRG 456. The 11 cases found in MS–DRG 457 also have a shorter average length of stay (5.0 days versus 6.1 days) and lower average costs ($47,221 versus $52,179). For MS–DRG 458, we found 6 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device with a comparable average length of stay (3.0 days versus 3.1 days) and higher average costs ($53,140 versus $39,260) compared to the average costs of all the cases in MS–DRG 458, with a difference in average costs of $13,880 ($53,140 − $39,260 = $13,880) for the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device.

For MS–DRGs 459 and 460, we found a total of 65 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device with an average length of stay of 2.7 days and average costs of $57,128. The single case found in MS–DRG 459 had a longer average length of stay (22 days versus 9.6 days) and higher average costs ($288,499 versus $53,192) compared to the average costs of all the cases in MS–DRG 459. For MS–DRG 460, the 64 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device had a shorter average length of stay (2.4 days versus 3.4 days) and higher average cost ($53,513 versus $32,586), compared to all the cases in MS–DRG 460, with a difference in average costs of $20,927 ($53,513 − $32,586 = $20,927) for the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device.

As discussed in the FY 2024 final rule, the manufacturer expressed concern that there may be unintentional miscoded claims from providers with whom they do not have an explicit relationship and, as previously discussed, subsequently provided the list of providers with which it indicated it has an explicit relationship to assist in our ongoing review. In connection with the list of providers submitted, the manufacturer also resubmitted claims data from the Standard Analytical File (SAF) that included FY 2022 claims and the first two quarters (discharges beginning October 1, 2022 through March 31, 2023) of FY 2023 from these providers. We note that the list of providers the manufacturer submitted to us was considered applicable for the dates of service in connection with the resubmitted claims data. The manufacturer stated that the list of providers with which it has an explicit relationship is subject to change on a weekly basis as additional providers begin to use the technology. The manufacturer also clarified that the external customer data it had previously referenced in connection with the FY 2024 rulemaking that was received directly from the providers with which it has an explicit relationship is Medicare data. We reviewed the September update of the FY 2022 MedPAR file and compared it against the claims data file with the list of providers submitted by the manufacturer for FY 2022. In this updated analysis of the September update of the FY 2022 MedPAR claims data, we were able to confirm that the majority of the cases for the providers with which the manufacturer indicated it has an explicit relationship matched the claims data in our FY 2022 MedPAR file. However, we identified 3 claims that appeared in the manufacturer's file that were not found in our FY 2022 MedPAR file and could not be validated. Next, we reviewed the September update of the FY 2023 MedPAR file and compared it against the claims data file with the list of providers submitted by the manufacturer for the first two quarters of FY 2023. We were able to confirm that the majority of the cases for the providers with which the manufacturer indicated it has an explicit relationship matched the claims data in our FY 2023 MedPAR file. However, we identified 2 claims that appeared in the manufacturer's file that were not found in our FY 2023 MedPAR file and also could not be validated.

In our analysis of the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 from the September update of the FY 2023 MedPAR file, we also reviewed the findings for cases identified based on the list of providers with which the manufacturer indicated it has an explicit relationship and cases based on other providers, (that is, those providers not included on the manufacturer's list), and compared those to the findings from all the cases we identified in the September update of the FY 2023 MedPAR file reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460. The findings from our analysis are shown in the following table. We note that there were no cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device based on the list of providers submitted by the manufacturer in MS–DRG 456.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 453 All cases	4,066	9.5	$80,420
MS-DRG 453 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	26	9.8	$99,162
MS-DRG 453 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	10	10.5	$118,863
MS-DRG 453 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	16	9.4	$86,849
MS-DRG 454 All cases	20,425	4.3	$54,983
MS-DRG 454 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	129	4.9	$71,527
MS-DRG 454 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	48	6.3	$81,680
MS-DRG 454 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	81	4.1	$65,510
MS-DRG 455 All cases	17,000	2.6	$41,015
MS-DRG 455 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	87	2.6	$54,922
MS-DRG 455 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	14	2.5	$61,637
MS-DRG 455 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	73	2.6	$53,634
MS-DRG 456 All cases	1,475	12.6	$76,060
MS-DRG 456 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	2	8.5	$69,009
MS-DRG 457 All cases	3,730	6.1	$52,179
MS-DRG 457 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	11	5	$47,221
MS-DRG 457 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	2	4.5	$53,113
MS-DRG 457 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	9	5.1	$45,912
MS-DRG 458 All cases	1,260	3.1	$39,260
MS-DRG 458 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	6	3	$53,140
MS-DRG 458 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	3	3.33	$52,760
MS-DRG 458 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	3	2.7	$53,520
MS-DRG 459 All cases	3,152	9.6	$53,192
MS-DRG 459 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	1	22	$288,499
MS-DRG 459 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	1	22	$288,499
MS-DRG 460 All cases	28,698	3.4	$32,586
MS-DRG 460 Cases reporting a custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file	64	2.4	$53,513
MS-DRG 460 Cases reporting a custom-made anatomically designed interbody fusion device based on the manufacturer provider list	13	2.6	$62,829
MS-DRG 460 Cases reporting a custom-made anatomically designed interbody fusion device based on other providers	51	2.3	$51,138

For MS–DRG 453, the data show that of the 26 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 10 cases were reported based on the manufacturer's provider list, and 16 cases were reported based on other providers. The average length of stay is longer (10.5 days versus 9.4 days), and the average costs are higher ($118,863 versus $86,849) for the 10 cases reported based on the manufacturer's provider list compared to the 16 cases that were reported based on other providers. For MS–DRG 454, the data show that of the 129 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 48 cases were reported based on the manufacturer's provider list, and 81 cases were reported based on other providers. The average length of stay is longer (6.3 days versus 4.1 days), and the average costs are higher ($81,680 versus $65,510) for the 48 cases reported based on the manufacturer's provider list compared to the 81 cases that were reported based on other providers. For MS–DRG 455, the data show that of the 87 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 14 cases were reported based on the manufacturer's provider list, and 73 cases were reported based on other providers. The average

length of stay is shorter (2.5 days versus 2.6 days), and the average costs are higher ($61,637 versus $53,634) for the 14 cases reported based on the manufacturer's provider list compared to the 73 cases that were reported based on other providers.

For MS–DRG 456, the data show that of the 2 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, there were no cases reported based on the manufacturer's provider list and the 2 cases reported were based on other providers. For MS–DRG 457, the data show that of the 11 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 2 cases were reported based on the manufacturer's provider list, and 9 cases were reported based on other providers. The average length of stay is shorter (4.5 days versus 5.1 days), and the average costs are higher ($53,113 versus $45,912) for the 2 cases reported based on the manufacturer's provider list compared to the 9 cases that were reported based on other providers. For MS–DRG 458, the data show that of the 6 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 3 cases were reported based on the manufacturer's provider list, and 3 cases were reported based on other providers. The average length of stay is longer (3.3 days versus 2.7 days), and the average costs are lower ($52,760 versus $53,520) for the 3 cases reported based on the manufacturer's provider list compared to the 3 cases that were reported for other providers.

For MS–DRG 459, the data show that the single case found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file was based on the manufacturer's provider list. There were no cases reported based on other providers. For MS–DRG 460, the data show that of the 64 cases found to report the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the FY 2023 MedPAR file, 13 cases were reported based on the manufacturer's provider list, and 51 cases were reported based on other providers. The average length of stay is comparable (2.6 days versus 2.3 days), and the average costs are higher ($62,829 versus $51,138) for the 13 cases reported based on the manufacturer's provider list compared to the 51 cases that were reported from other providers.

We considered these data findings with regard to the concerns expressed by the manufacturer that there may be unintentional miscoded claims reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from providers with whom the manufacturer does not have an explicit relationship. Based on our review and analysis of the claims data, we are unable to confirm that the claims from these providers with whom the manufacturer indicated that it does not have an explicit relationship are miscoded.

We note that, while a newly established ICD–10 code may be associated with an application for new technology add-on payment, such codes are not generally established to be product specific. If, after consulting the official coding guidelines, a provider determines that an ICD–10 code associated with a new technology add-on payment describes the technology that they are billing, the hospital may report the code and be eligible to receive the associated add-on payment. Providers are responsible for ensuring that they are billing correctly for the services they render. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), coding advice is issued independently from payment policy. We also note that, historically, we have not provided coding advice in rulemaking with respect to policy (82 FR 38045). As one of the Cooperating Parties for ICD–10, we collaborate with the American Hospital Association (AHA) through the *Coding Clinic for ICD–10–CM and ICD–10–PCS* to promote proper coding. We recommend that an entity seeking coding guidance submit any questions pertaining to correct coding to the AHA.

Accordingly, after review of the list of providers and associated claims data submitted by the manufacturer, and our analysis of the MedPAR data, we believe these MedPAR data are appropriate for our FY 2025 analysis. Therefore, in assessing the request for reassignment of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the lower severity MS–DRG 455 to the higher severity MS–DRG 453, from the lower severity MS–DRG 458 to the higher severity level MS–DRG 456 when a diagnosis of malalignment is reported, and cases from MS–DRGs 459 and 460 to MS–DRG 456 for FY 2025, we considered all the claims data reporting the performance of a spinal fusion procedure, including those spinal fusion procedures using an aprevo™ custom-made anatomically designed interbody fusion device as identified in the September update of the FY 2023 MedPAR file for these MS–DRGs. Consequently, our analysis also included claims based on the list of providers submitted by the manufacturer as well as other providers.

Based on the findings from our analysis and clinical review, we do not believe the requested reassignments are supported. Specifically, it would not be appropriate to propose to reassign the 87 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the lower severity level MS–DRG 455 (without CC/MCC) with an average length of stay of 2.6 days and average costs of $54,922 to the higher severity level MS–DRG 453 (with MCC) with an average length of stay of 9.5 days and average costs of $80,420. If we were to propose to reassign the 87 cases from the lower severity MS–DRG 455 to the higher severity MS–DRG 453, the MS–DRGs would no longer be clinically coherent with regard to severity of illness of the patients, and the cases would reflect a difference in resource utilization, as demonstrated by the difference in average costs of approximately $25,498 ($80,420 − $54,922 = $25,498), as well as a difference in average length of stay (2.6 days versus 9.5 days) compared to all the cases in MS–DRG 453. Similarly, it would not be appropriate to propose to reassign the 6 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from the lower severity level MS–DRG 458 (without CC/MCC) with an average length of stay of 3.0 days and average costs of $53,140 to the higher severity level MS–DRG 456 (with MCC) with an average length of stay of 12.6 days and average costs of $76,060. If we were to propose to reassign the 6 cases from the lower severity MS–DRG 458 to the higher severity MS–DRG 456, the MS–DRGs would no longer be clinically coherent with regard to severity of illness of the patients and the cases would reflect a difference in resource utilization, as demonstrated by the difference in average costs of approximately $22,920 ($76,060 − $53,140 = $22,920) as well as a difference in average length of stay

(3.0 days versus 12.6 days) compared to all the cases in MS–DRG 456. Finally, it would not be appropriate nor consistent with the definition of the MS–DRGs to propose to reassign the 65 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device from MS–DRGs 459 and 460 with an average length of stay of 2.7 days and average costs of $57,128 to MS–DRG 456. In addition to the cases reflecting a difference in resource utilization as demonstrated by the difference in average costs of approximately $18,932 ($76,060 − $57,128 = $18,932) as well as having a shorter average length of stay (2.7 days versus 12.6 days), we note that the logic for case assignment to MS–DRGs 456, 457, and 458 is specifically defined by principal diagnosis logic. As such, cases grouping to this set of MS–DRGs require a principal diagnosis of spinal curvature, malignancy, or infection, or an extensive fusion procedure. Therefore, it would not be clinically appropriate to propose to reassign cases from MS–DRGs 459 and 460 that do not have a principal diagnosis of spinal curvature, malignancy, or infection, or an extensive fusion procedure, and are not consistent with the logic for case assignment to MS–DRG 456.

In light of the higher average costs of the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 453, 454, 455, 458, and 460, we further reviewed the claims data for cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in these MS–DRGs and identified a wide range in the average length of stay and average costs. For example, in MS–DRG 453, the average length of stay for the 26 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 3.0 days to 27 days and the average costs ranged from $28,054 to $177,919. In MS–DRG 454, the average length of stay for the 129 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 1.0 day to 16 days and the average costs ranged from $10,242 to $316,780. In MS–DRG 455, the average length of stay for the 87 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 1.0 day to 9.0 days and the average costs ranged from $7,961 to $216,200. In MS–DRG 456, the average length of stay for the 2 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device were 8.0 days and 9.0 days, respectively, with average costs of $107,457 and $30,560, respectively. In MS–DRG 457, the average length of stay for the 11 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 1.0 day to 17 days and the average costs ranged from $25,955 to $89,176. In MS–DRG 458, the average length of stay for the 6 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 1.0 day to 5.0 days and the average costs ranged from $33,165 to $78,720. In MS–DRG 459, the length of stay for the single case reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device was 22 days with a cost of $288,499, indicating it is an outlier. In MS–DRG 460, the average length of stay for the 64 cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device ranged from 1.0 day to 8.0 days and the average costs ranged from $8,981 to $325,104.

In our analysis of the claims data for MS–DRGs 453, 454, and 455, we also identified a number of cases for which additional spinal fusion procedures were performed, beyond the logic for case assignment to the respective MS–DRG. For example, the logic for case assignment to MS–DRGs 453, 454, and 455 requires at least one anterior column fusion and one posterior column fusion (that is, combined anterior and posterior fusion). We note that the aprevo™ custom-made anatomically designed interbody fusion device is used in the performance of an anterior column fusion. Findings from our analysis of MS–DRG 453 show that of the 26 cases reporting a combined anterior and posterior fusion (including an aprevo™ custom-made anatomically designed interbody fusion device), 24 cases also reported another spinal fusion procedure. We categorized these cases as ''multiple level fusions'' where another procedure code describing a spinal fusion procedure was reported in addition to the combined anterior and posterior fusion procedure codes. Findings from our analysis of MS–DRG 454 show that of the 129 cases reporting a combined anterior and posterior fusion (including an aprevo™ custom-made anatomically designed interbody fusion device), 100 cases also reported another spinal fusion procedure. Lastly, findings from our analysis of MS–DRG 455 show that of the 87 cases reporting a combined anterior and posterior fusion (including an aprevo™ custom-made anatomically designed interbody fusion device), 51 cases also reported another spinal fusion procedure.

While the findings from our analysis indicate a wide range in the average length of stay and average costs for cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device, we believe the increase in resource utilization for certain cases may be partially attributable to the performance of multiple level fusion procedures and, specifically for MS–DRGs 453 and 454, the reporting of secondary diagnosis MCC and CC conditions. Our analysis of the data for MS–DRGs 453 and 454 show that the cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device also reported multiple MCC and CC conditions, which we believe may be an additional contributing factor to the increase in resource utilization for these cases, combined with the reported performance of multiple level fusions.

In our analysis of the data for MS–DRGs 453, 454, and 455 and cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device, we also identified other procedures that were reported, some of which are designated as operating room (O.R.) procedures, that we believe may be another contributing factor to the increase in resource utilization and complexity for these cases. (We note that because a discectomy is frequently performed in connection with a spinal fusion procedure, we did not consider these procedures as contributing factors to consumption of resources in these spinal fusion cases). In the tables that follow we provide a list of the top 5 MCC and CC conditions, as well as the top 5 O.R. procedures (excluding discectomy) reported in MS–DRGs 453, 454, and 455 that we believe may be contributing factors to the increase in resource utilization and complexity for these cases. We note that the logic for case assignment to MS–DRG 453 includes the reporting of at least one

secondary diagnosis MCC condition (''with MCC'') and cases that group to this MS–DRG may also report secondary diagnosis CC conditions. We are providing the frequency data for both the top 5 secondary diagnosis MCC conditions and the top 5 secondary diagnosis CC conditions, in addition to the top 5 O.R. procedures (excluding discectomy) that were reported for spinal fusion cases with an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRG 453. Because the logic for case assignment to MS–DRG 454 includes the reporting of at least one secondary diagnosis CC condition (''with CC'') we are providing the top 5 secondary diagnosis CC conditions and the top 5 O.R. procedures (excluding discectomy) that were reported for spinal fusion cases with an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRG 454. We note that the logic for case assignment to MS–DRG 455 is ''without CC/MCC'' and does not include any secondary diagnosis MCC or CC conditions, therefore, we are only providing a table with the top 5 O.R. procedures (excluding discectomy) reported for that MS–DRG in addition to a spinal fusion procedure.

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MS-DRG 453 Top 5 Secondary Diagnosis MCC Conditions Reported		
ICD-10-CM Code	**Description**	**Frequency**
J95.2	Acute pulmonary insufficiency following nonthoracic surgery	5
G92.8	Other toxic encephalopathy	5
R57.1	Hypovolemic shock	4
J18.9	Pneumonia, unspecified organism	4
J81.0	Acute pulmonary edema	2

MS-DRG 453 Top 5 Secondary Diagnosis CC Conditions Reported		
ICD-10-CM Code	**Description**	**Frequency**
D6.2	Acute posthemorrhagic anemia	17
E87.4	Mixed disorder of acid-base balance	4
N17.9	Acute kidney failure, unspecified	3
E87.1	Hypo-osmolality and hyponatremia	3
K56.7	Ileus, unspecified	3

MS-DRG 453 Top 5 Operating Room Procedures Reported		
ICD-10-PCS Code	**Description**	**Frequency**
01NB0ZZ	Release lumbar nerve, open approach	2,011
00NY0ZZ	Release lumbar spinal cord, open approach	754
01NR0ZZ	Release sacral nerve, open approach	538
0QP004Z	Removal of internal fixation from lumbar vertebra, open approach	379
00NW0ZZ	Release cervical spinal cord, open approach	380

MS-DRG 454 Top 5 Secondary Diagnosis CC Conditions Reported		
ICD-10-CM Code	**Description**	**Frequency**
D6.2	Acute posthemorrhagic anemia	66
E871	Hypo-osmolality and hyponatremia	19
K567	Ileus, unspecified	13
M960	Pseudarthrosis after fusion or arthrodesis	10
J9811	Atelectasis	10

MS-DRG 454 Top 5 Operating Room Procedures Reported		
ICD-10-PCS Code	**Description**	**Frequency**
00NY0ZZ	Release lumbar spinal cord, open approach	4,109
01NB0ZZ	Release lumbar nerve, open approach	12,389
0SP004Z	Removal of internal fixation device from lumbar vertebral joint, open approach	1,381
0QP004Z	Removal of internal fixation device from lumbar vertebra, open approach	2,398
01NR0ZZ	Release sacral nerve, open approach	3,098

MS-DRG 455 Top 5 Operating Room Procedures Reported		
ICD-10-PCS Code	**Description**	**Frequency**
0QP004Z	Removal of internal fixation device from lumbar vertebra, open approach	1,184
0SP004Z	Removal of internal fixation device from lumbar vertebral joint, open approach	756
01NR0ZZ	Release sacral nerve, open approach	2,143
00NY0ZZ	Release lumbar spinal cord, open approach	3,192
01NB0ZZ	Release lumbar nerve, open approach	10,405

As previously summarized, our analysis of the claims data for cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device demonstrated a low volume of cases and higher average costs in comparison to all the cases in their respective MS–DRGs (that is, in MS–DRGs 453, 454, 455, 458, 459, and 460). Therefore, we expanded our analysis to include all spinal fusion cases in MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 to identify and further examine the cases reporting multiple level fusions versus single level fusions, multiple MCCs or CCs, and other O.R. procedures as we believed that clinically, all of these factors may contribute to increases in resource utilization, severity of illness and technical complexity.

We began our expanded analysis with MS–DRGs 453, 454, and 455. Based on the findings for a subset of the cases (that is, the subset of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device) in these MS–DRGs as previously discussed, and our review of the logic for case assignment to these MS–DRGs, we developed three categories of spinal fusion procedures to further examine. The first category was for the single level combined anterior and posterior fusions except cervical, the second category was for the multiple level combined anterior and posterior fusions except cervical and the third category was for the combined anterior and posterior cervical spinal fusions. We refer the reader to Table 6P.2d for the list of procedure codes we identified to categorize the single level combined anterior and posterior fusions except cervical, Table 6P.2e for the list of procedure codes we identified to categorize the multiple level combined anterior and posterior fusions except cervical, and Table 6P.2f for the list of procedure codes we identified to categorize the combined anterior and posterior cervical spinal fusions. Findings from our analysis are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 453 All cases	4,066	9.5	$80,420
MS-DRG 453 Cases with single level combined anterior and posterior fusion except cervical	791	6.4	$47,031
MS-DRG 453 Cases with multiple level combined anterior and posterior fusion except cervical	2,664	9.6	$91,358
MS-DRG 453 Cases with combined anterior and posterior cervical fusion	587	12.5	$75,077
MS-DRG 454 All cases	20,425	4.3	$54,983
MS-DRG 454 Cases with single level combined anterior and posterior fusion except cervical	6,481	3.4	$38,107
MS-DRG 454 Cases with multiple level combined anterior and posterior fusion except cervical	12,498	4.8	$64,065
MS-DRG 454 Cases with combined anterior and posterior cervical fusion	1,391	5.1	$52,274
MS-DRG 455 All cases	17,000	2.6	$41,015
MS-DRG 455 Cases with single level combined anterior and posterior fusion except cervical	8,787	2.3	$33,010
MS-DRG 455 Cases with multiple level combined anterior and posterior fusion except cervical	7,855	3.0	$50,097
MS-DRG 455 Cases with combined anterior and posterior cervical fusion	345	2.9	$37,515

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The data show that across MS–DRGs 453, 454, and 455, cases reporting multiple level combined anterior and posterior fusion procedures have a comparable average length of stay (9.6 days versus 9.5 days, 4.8 days versus 4.3 days, and 3.0 days versus 2.6 days, respectively) and higher average costs ($91,358 versus $80,420, $64,065 versus $54,983, and $50,097 versus $41,015) compared to all the cases in MS–DRGs 453, 454, and 455, respectively. The data also show that across MS–DRGs 453, 454, and 455, cases reporting multiple level combined anterior and posterior fusion procedures have a longer average length of stay (9.6 days versus 6.4 days, 4.8 days versus 3.4 days, and 3.0 days versus 2.3 days, respectively) and higher average costs ($91,358 versus $47,031, $64,065 versus $38,107, and $50,097 versus $33,010, respectively) compared to cases reporting a single level combined anterior and posterior fusion. For cases reporting a combined anterior and posterior cervical fusion across MS–DRGs 453 and 454, the data show a longer average length of stay (12.5 days versus 9.5 days, and 5.1 days versus 4.3 days, respectively) compared to all the cases in MS–DRGs 453 and 454 and a comparable average length of stay (2.9 days versus 2.6 days) for cases reporting a combined anterior and posterior cervical fusion in MS–DRG 455. The data also show that across MS–DRGs 453, 454, and 455, cases reporting a combined anterior and posterior cervical fusion have higher average costs ($75,077 versus $47,031, $52,274 versus $38,107, and $37,515 versus $33,010, respectively) compared to the single level combined anterior and posterior fusion cases.

The data also reflect that in applying the logic that was developed for the three categories of spinal fusion in MS–DRGs 453, 454, and 455 (single level combined anterior and posterior fusion except cervical, multiple level combined anterior and posterior fusion except cervical, and combined anterior and posterior cervical fusion), there is a

small redistribution of cases from the current MS–DRGs 453, 454, and 455 to other spinal fusion MS–DRGs because the logic for case assignment to MS–DRGs 453, 454, and 455 is currently satisfied with any one procedure code from the anterior spinal fusion logic list and any one procedure code from the posterior spinal fusion logic list, however, the logic lists that were developed for our analysis using the three categories of spinal fusion are comprised of specific procedure code combinations to satisfy the criteria for case assignment to any one of the three categories developed. For example, based on our analysis of MS–DRG 453 using the September update of the FY 2023 MedPAR file, the total number of cases found in MS–DRG 453 is 4,066 and with application of the logic for each of the three categories, the total number of cases in MS–DRG 453 is 4,042 (791 + 2,664 + 587 = 4,042), a difference of 24 cases. Using the September update of the FY 2023 MedPAR file, the total number of cases found in MS–DRG 454 is 20,425 and with application of the logic for each of the three categories, the total number of cases in MS–DRG 454 is 20,370 (6,481 + 12,498 + 1,391 = 20,370), a difference of 55 cases. Lastly, using the September update of the FY 2023 MedPAR file, the total number of cases found in MS–DRG 455 is 17,000 and with application of the logic for each of the three categories, the total number of cases in MS–DRG 455 is 16,987 (9,763 + 6,879 + 345 = 16,987), a difference of 13 cases. Overall, a total of 92 cases are redistributed from MS–DRGs 453, 454, and 455 to other spinal fusion MS–DRGs.

The findings from our analysis of MS–DRGs 453, 454, and 455 are consistent with the expectation that clinically, the greater the number of spinal fusion procedures performed during a single procedure (for example, intervertebral levels fused), the greater the consumption of resources expended. We believe the use of interbody fusion cages, other types of spinal instrumentation, operating room time, comorbidities, pharmaceuticals, and length of stay may all be contributing factors to resource utilization for spinal fusion procedures. In addition, it is expected that as a result of potential changes to the logic for case assignment to a MS–DRG, there will be a redistribution of cases among the MS–DRGs.

Based on our review and analysis of the spinal fusion cases in MS–DRGs 453, 454, and 455, we believe new MS–DRGs are warranted to differentiate between multiple level combined anterior and posterior spinal fusions except cervical, single level combined anterior and posterior spinal fusions except cervical, and combined anterior and posterior cervical spinal fusions, to more appropriately reflect utilization of resources for these procedures, including those performed with an aprevo™ custom-made anatomically designed interbody fusion device. We note that the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device as identified by any one of the 12 previously listed procedure codes would not be reported for a cervical spinal fusion procedure as reflected in Table 6P.2f associated with this proposed rule and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

To compare and analyze the impact of our suggested modifications, we ran simulations using claims data from the September 2023 update of the FY 2023 MedPAR file. The following table illustrates our findings for all 23,017 cases reporting procedure codes describing multiple level combined anterior and posterior spinal fusions.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	23,017	4.7	$62,457

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG was met. The following table illustrates our findings.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,664	9.6	$91,358
With CC	12,498	4.8	$64,065
Without CC/MCC	7,855	3.0	$50,097

For the proposed new MS–DRGs, there is (1) at least 500 or more cases in the MCC group, the CC subgroup, and in the without CC/MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup, the CC subgroup, and in the without CC/MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the CC subgroup and between the CC group and NonCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the with CC subgroup and between the CC subgroup and NonCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

As a result, for FY 2025, we are proposing to create new MS–DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC), new MS–DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and new MS–DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC). The following table reflects a simulation of the proposed new MS–DRGs.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG 426	2,664	9.6	$91,358
Proposed new MS-DRG 427	12,498	4.8	$64,065
Proposed new MS-DRG 428	7,855	3.0	$50,097

The next step in our analysis of the impact of our suggested modifications to MS–DRGs 453, 454, and 455 was to review the cases reporting single combined anterior and posterior cervical fusions. The following table illustrates our findings for all 16,059 cases reporting procedure codes describing single level combined anterior and posterior spinal fusions.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	16,059	2.9	$35,758

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that at least 5% or more of the cases are in the MCC subgroup. It also failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC (without CC/MCC) subgroup. The following table illustrates our findings.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	791	6.4	$47,031
With CC	6,481	3.4	$38,107
Without CC/MCC	8,787	2.3	$33,010

As discussed in section II.C.1.b. of the preamble of this proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We note that, as shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 5% or more of the cases in the with MCC subgroup.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	791	6.4	$47,031
Without MCC	15,268	2.8	$35,174

We then applied the criteria for a two-way split for the ''with CC/MCC and without CC/MCC'' subgroups. As shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the ''with CC/MCC and without CC/MCC'' subgroup.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With CC/MCC	7,272	3.7	$39,078
Without CC/MCC	8,787	2.3	$33,010

We note that because the criteria for both of the two-way splits failed, a split (or CC subgroup) is not warranted for the proposed new base MS–DRG. As a result, for FY 2025, we are proposing to create new base MS–DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical). The following table reflects a simulation of the proposed new base MS–DRG.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed MS-DRG 402	16,059	2.9	$35,758

For the final step in our analysis of the impact of our suggested modifications to MS–DRGs 453, 454, and 455 we reviewed the cases reporting combined anterior and posterior cervical fusions. The following table illustrates our findings for all 2,323 cases reporting procedure codes

describing combined anterior and posterior cervical spinal fusions.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	2,323	6.6	$55,844

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that that there be at least 500 cases in the NonCC subgroup.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	587	12.5	$75,077
With CC	1,391	5.1	$52,274
Without CC/MCC	345	2.9	$37,515

As discussed in section II.C.1.b. of the preamble of this proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We note that, as shown in the table that follows, a two-way split of this proposed new base MS–DRG was met. For the proposed MS–DRGs, there is at least (1) 500 or more cases in the MCC group and in the without MCC subgroup; (2) 5 percent or more of the cases in the MCC group and in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table illustrates our findings for the suggested MS–DRGs with a two-way severity level split.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	587	12.5	$75,077
Without MCC	1,736	4.6	$49,341

Accordingly, because the criteria for the two-way split were met, we believe a split (or CC subgroup) is warranted for the proposed new base MS–DRG. As a result, for FY 2025, we are proposing to create new MS–DRG 429 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC) and new MS–DRG 430 (Combined Anterior and Posterior Cervical Spinal Fusion without MCC). The following table reflects a simulation of the proposed new MS–DRGs.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG 429	587	12.5	$75,077
Proposed new MS-DRG 430	1,736	4.7	$49,341

We then analyzed the cases reporting spinal fusion procedures in MS–DRGs 456, 457, and 458. As previously described, the logic for case assignment to MS–DRGs 456, 457, and 458 is defined by principal diagnosis logic and extensive fusion procedures. Cases reporting a principal diagnosis of spinal curvature, malignancy, or infection or an extensive fusion procedure will group to these MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for complete documentation of the GROUPER logic for MS–DRGs 456, 457, and 458.

As also previously described, in our initial analysis of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device, the 13 cases we found in MS–DRGs 456 and 457 (2 + 11 = 13, respectively) appeared to be grouping appropriately, however, the average costs for the 6 cases found in MS–DRG 458 showed a difference of approximately $13,880. Because of the low volume of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in the ''without CC/MCC'' MS–DRG 458, and the low volume of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 456, 457, and 458 overall (2 + 11 + 6 = 19), for this expanded review of the claims data, we are sharing the results of our analysis in association with cases reporting extensive fusion procedures in MS–DRGs 456, 457, and 458. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 456 All cases	1,475	12.6	$76,060
MS-DRG 456 Cases reporting an extensive fusion	332	11.5	$89,773
MS-DRG 457 All cases	3,730	6.1	$52,179
MS-DRG 457 Cases reporting an extensive fusion	171	6.6	$75,588
MS-DRG 458 All cases	1,260	3.1	$39,260
MS-DRG 458 Cases reporting an extensive fusion	146	3.8	$48,035

The data show that the 332 cases reporting an extensive fusion procedure in MS–DRG 456 have a shorter average length of stay (11.5 days versus 12.6 days) and higher average costs ($89,773 versus $76,060) compared to all the cases in MS–DRG 456. For MS–DRG 457, the data show that the 171 cases reporting an extensive fusion have a comparable average length of stay (6.6 days versus 6.1 days) and higher average costs ($75,588 versus $52,179) compared to all the cases in MS–DRG 457. Lastly, for MS–DRG 458, the data show that the 146 cases reporting an extensive fusion procedure have a comparable average length of stay (3.8 days versus 3.1 days) and higher average costs ($48,035 versus $39,260) compared to all the cases in MS–DRG 458.

We believe that over time, the volume of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device in MS–DRGs 456, 457, and 458 may increase and we could consider further in the context of the cases reporting an extensive fusion procedure. However, due to the logic for case assignment to these MS–DRGs also being defined by diagnosis code logic, additional analysis would be needed prior to considering any modification to the current structure of these MS–DRGs. As we continue to evaluate how we may refine these spinal fusion MS–DRGs, we are also seeking public comments and feedback on other factors that should be considered in the potential restructuring of MS–DRGs 456, 457, and 458. Thus, for FY 2025, we are proposing to maintain the current structure of MS–DRGs 456, 457, and 458, without modification. Feedback and other suggestions for future rulemaking may be submitted by October 20, 2024 and directed to MEARIS™ at *https://mearis.cms.gov/public/home.*

Next, we performed an expanded analysis for spinal fusion cases reported in MS–DRGs 459 and 460. We note that cases grouping to MS–DRG 459 have at least one secondary diagnosis MCC condition reported (''with MCC'') and because MS–DRG 460 is ''without MCC'', cases grouping to this MS–DRG may include the reporting of at least one secondary diagnosis CC condition (in addition to cases that may not report a CC (for example, NonCC)). Based on the findings for a subset of the cases (that is, the subset of cases reporting the performance of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device) in these MS–DRGs as previously discussed, and our review of the logic for case assignment to these MS–DRGs, we developed two categories of spinal fusion procedures to further examine. The first category was for the single level spinal fusions except cervical, and the second category was for the multiple level spinal fusions except cervical. We refer the reader to Table 6P.2g for the list of procedure codes we identified to categorize the single level spinal fusions except cervical and Table 6P.2h for the list of procedure codes we identified to categorize the multiple level spinal fusions except cervical. Findings from our analysis are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 459 All cases	3,152	9.6	$53,192
MS-DRG 459 Cases reporting single level spinal fusion except cervical	1,098	8.9	$46,031
MS-DRG 459 Cases reporting multiple level spinal fusion except cervical	2,069	10.1	$57,209
MS-DRG 460 All cases	28,698	3.4	$32,586
MS-DRG 460 Cases reporting single level spinal fusion except cervical	14,058	3.0	$28,110
MS-DRG 460 Cases reporting multiple level spinal fusion except cervical	14,677	3.9	$36,932

The data show that the 2,069 cases reporting a multiple level spinal fusion except cervical in MS–DRG 459 have a longer average length of stay (10.1 days versus 9.6 days) and higher average costs ($57,209 versus $53,192) when compared to all the cases in MS–DRG 459. The data also show that the 2,069 cases reporting a multiple level spinal fusion except cervical in MS–DRG 459 have a longer average length of stay (10.1 days versus 8.9 days) and higher average costs ($57,209 versus $46,031) when compared to the 1,098 cases reporting a single level spinal fusion except cervical in MS–DRG 459. For MS–DRG 460, the data show that the 14,677 cases reporting a multiple level spinal fusion except cervical have a comparable average length of stay (3.9 days versus 3.4 days) and higher average costs ($36,932 versus $32,586) when compared to all the cases in MS–DRG 460. The data also show that the 14,677 cases reporting a multiple level spinal fusion except cervical have a comparable average length of stay (3.9 days versus 3.0 days) and higher average costs ($36,932 versus $28,110) when compared to the 14,058 cases reporting a single level spinal fusion except cervical in MS–DRG 460.

Based on our review and analysis of the spinal fusion cases in MS–DRGs 459 and 460, we believe new MS–DRGs are warranted to differentiate between multiple level spinal fusions except cervical and single level spinal fusions except cervical to more appropriately reflect utilization of resources for these procedures, including those performed with an aprevo™ custom-made anatomically designed interbody fusion device.

To compare and analyze the impact of our suggested modifications, we ran simulations using claims data from the September 2023 update of the FY 2023 MedPAR file. The following table illustrates our findings for all 16,746 cases reporting procedure codes describing multiple level spinal fusions except cervical.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	16,746	4.6	$39,438

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the proposed new base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC (without CC/MCC) subgroup. The following table illustrates our findings.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,069	10.1	$57,209
With CC	8,695	4.6	$38,574
Without CC/MCC	5,982	2.8	$34,546

As discussed in section II.C.1.b. of the preamble of this proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We note that, as shown in the table that follows, a two-way split of this proposed new base MS–DRG was met. For the proposed MS–DRGs, there is at least (1) 500 or more cases in the MCC group and in the without MCC subgroup; (2) 5 percent or more of the cases in the MCC group and in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table illustrates our findings for the suggested MS–DRGs with a two-way severity level split.

Proposed New MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,069	10.1	$57,209
Without MCC	14,677	3.9	$36,932

As a result, for FY 2025, we are proposing to create new MS–DRGs 447 (Multiple Level Spinal Fusion Except Cervical with MCC) and new MS–DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC). We are also proposing to revise the title for existing MS–DRGs 459 and 460 to ''Single Level Spinal Fusion Except Cervical with MCC and without MCC'', respectively. This proposal would better differentiate the resource utilization, severity of illness and technical complexity between single level and multiple level spinal fusions that do not include cervical spinal fusions in the logic for case assignment. The following table reflects a simulation of the proposed new MS–DRGs.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG 447	2,069	10.1	$57,209
Proposed new MS-DRG 448	14,677	3.9	$36,932

In conclusion, we are proposing to delete MS–DRGs 453, 454, and 455 and proposing to create 8 new MS–DRGs. We are proposing to create new MS–DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC), MS–DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), MS–DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC), MS–DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical), MS–DRG 429 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC), MS–DRG 430 (Combined Anterior and Posterior Cervical Spinal Fusion without MCC), MS–DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC) and MS–DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC) for FY 2025. We are proposing the logic for case assignment to these proposed new MS–DRGs as displayed in Table 6P.2d, Table 6P.2e, Table 6P.2f, Table 6P.2g, and Table 6P.2h. We are also proposing to revise the title for MS–DRGs 459 and

460 to ''Single Level Spinal Fusion Except Cervical with MCC and without MCC'', respectively. Lastly, as discussed in section II.C.14 of the preamble of this proposed rule, we are proposing conforming changes to the surgical hierarchy for MDC 08.

7. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Resection of Right Large Intestine

We identified an inconsistency in the MDC and MS–DRG assignment of procedure codes describing resection of the right large intestine and resection of the left large intestine with an open and percutaneous endoscopic approach. ICD–10–PCS procedure codes 0DTG0ZZ (Resection of left large intestine, open approach) and 0DTG4ZZ (Resection of left large intestine, percutaneous endoscopic approach) are currently assigned to MDC 10 in MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). However, the procedure codes that describe resection of the right large intestine with an open or percutaneous endoscopic approach, 0DTF0ZZ (Resection of right large intestine, open approach) and 0DTF4ZZ (Resection of right large intestine, percutaneous endoscopic approach) are not assigned to MDC 10 in MS–DRGs 628, 629, and 630. To ensure clinical alignment and consistency, as well as appropriate MS–DRG assignment, we are proposing to add procedure codes 0DTF0ZZ and 0DTF4ZZ to MDC 10 in MS–DRGs 628, 629, and 630 effective October 1, 2024 for FY 2025.

8. MDC 15 (Newborns and Other Neonates With Conditions Originating in Perinatal Period): MS–DRG 795 Normal Newborn

We received a request to review the GROUPER logic that would determine the assignment of cases to MS–DRG 794 (Neonate with Other Significant Problems). The requestor stated that it appears that MS–DRG 794 is the default MS–DRG in MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period), as the GROUPER logic for MS–DRG 794 displayed in the ICD–10 MS–DRG Version 41.1 Definitions Manual is defined by a ''principal or secondary diagnosis of newborn or neonate, with other significant problems, not assigned to DRG 789 through 793 or 795''. The requestor expressed concern that defaulting to MS–DRG 794, instead of MS–DRG 795 (Normal Newborn), for assignment of cases in MDC 15 could contribute to overpayments in healthcare by not aligning the payment amount to the appropriate level of care in newborn cases. The requestor recommended that CMS update the GROUPER logic that would determine the assignment of cases to MS–DRGs in MDC 15 to direct all cases that do not have the diagnoses and procedures as specified in the Definitions Manual to instead be grouped to MS–DRG 795.

Specifically, the requestor expressed concern that a newborn encounter coded with a principal diagnosis code from ICD–10–CM category Z38 (Liveborn infants according to place of birth and type of delivery), followed by code P05.19 (Newborn small for gestational age, other), P59.9 (Neonatal jaundice, unspecified), Q38.1 (Ankyloglossia), Q82.5 (Congenital non-neoplastic nevus), or Z23 (Encounter for immunization) is assigned to MS–DRG 794. The requestor stated that they performed a detailed claim level study, and in their clinical assessment, newborn encounters coded with a principal diagnosis code from ICD–10–CM category Z38, followed by diagnosis code P05.19, P59.9, Q38.1, Q82.5, or Z23 in fact clinically describe normal newborn encounters and the case assignment should instead be to MS–DRG 795.

Our analysis of this grouping issue confirmed that when a principal diagnosis code from MDC 15, such as a diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery), is reported followed by ICD–10–CM code P05.19 (Newborn small for gestational age, other), Q38.1 (Ankyloglossia) or Q82.5 (Congenital non-neoplastic nevus), the case is assigned to MS–DRG 794.

However, as we examined the GROUPER logic that would determine an assignment of cases to MS–DRG 795, we noted the ''only secondary diagnosis'' list under MS–DRG 795 already includes ICD–10–CM codes P59.9 (Neonatal jaundice, unspecified) and Z23 (Encounter for immunization). Therefore, when a principal diagnosis code from MDC 15, such as a diagnosis code from category Z38 (Liveborn infants according to place of birth and type of delivery) is reported, followed by ICD–10–CM code P59.9 or Z23, the case is currently assigned to MS–DRG 795, not MS–DRG 794, as suggested by the requestor. We refer the reader to the ICD–10 MS–DRG Version 41.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software)* for complete documentation of the GROUPER logic for MS–DRGs 794 and 795.

Next, we reviewed the claims data from the September 2023 update of the FY 2023 MedPAR file; however, we found zero cases across MS–DRGs 794 and 795. We then examined the clinical factors. The description for ICD–10–CM diagnosis code P05.19 is ''Newborn small for gestational age, other'' and the inclusion term in the ICD–10–CM Tabular List of Diseases for this diagnosis code is ''Newborn small for gestational age, 2500 grams and over.'' We note that ''small-for-gestational age'' is diagnosed by assessing the gestational age and the weight of the baby after birth. There is no specific treatment for small-for-gestational-age newborns. Most newborns who are moderately small for gestational age are healthy babies who just happen to be on the smaller side. Unless the newborn is born with an infection or has a genetic disorder, most small-for-gestational-age newborns have no symptoms and catch up in their growth during the first year of life and have a normal adult height. Next, ICD–10–CM diagnosis code Q38.1 describes ankyloglossia, also known as tongue-tie, which is a condition that impairs tongue movement due to a restrictive lingual frenulum. In infants, tongue-tie is treated by making a small cut to the lingual frenulum to allow the tongue to move more freely. This procedure, called a frenotomy, can be done in a healthcare provider's office without anesthesia. Newborns generally recover within about a minute of the procedure, and pain relief is usually not indicated. Lastly, ICD–10–CM diagnosis code Q82.5 describes a congenital non-neoplastic nevus. A congenital nevus is a type of pigmented birthmark that appears at birth or during a baby's first year. Most congenital nevi do not cause health problems and may only require future monitoring.

In reviewing these three ICD–10–CM codes and the conditions they describe; we believe these diagnoses generally do not prolong the inpatient admission of the newborn and newborns with these diagnoses generally receive standard follow-up care after birth. Clinically, we agree with the requestor that newborn encounters coded with a principal diagnosis code from ICD–10–CM category Z38 (Liveborn infants according to place of birth and type of delivery), followed by code P05.19 (Newborn small for gestational age, other), Q38.1 (Ankyloglossia), or Q82.5 (Congenital non-neoplastic nevus) should not map to MS–DRG 794 (Neonate with Other Significant Problems) and should instead be assigned to MS–DRG 795 (Normal

Newborn). Therefore, for the reasons discussed, we are proposing to reassign diagnosis code P05.19 from the ''principal or secondary diagnosis'' list under MS–DRG 794 to the ''principal diagnosis'' list under MS–DRG 795 (Normal Newborn). We are also proposing to add diagnosis codes Q38.1 and Q82.5 to the ''only secondary diagnosis'' list under MS–DRG 795 (Normal Newborn). Under this proposal, cases with a principal diagnosis described by an ICD–10–CM code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes P05.19, Q38.1, or Q82.5 will be assigned to MS–DRG 795.

In response to the recommendation that CMS update the GROUPER logic that would determine an assignment of cases to MS–DRGs in MDC 15, we agree with the requestor that the GROUPER logic for MS–DRG 794 is defined by a ''principal or secondary diagnosis of newborn or neonate, with other significant problems, not assigned to DRG 789 through 793 or 795''. We acknowledge that MS–DRG 794 utilizes ''fall-through'' logic, meaning if a diagnosis code is not assigned to any of the other MS–DRGs, then assignment ''falls-through'' to MS–DRG 794. We have started to examine the GROUPER logic that would determine the assignment of cases to the MS–DRGs in MDC 15, including MS–DRGs 794 and 795, to determine where further refinements could potentially be made to better account for differences in clinical complexity and resource utilization. However, as we have noted in prior rulemaking (72 FR 47152), we cannot adopt the same approach to refine the newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these MS–DRGs. Additional time is needed to fully and accurately evaluate cases currently grouping to the MS–DRGs in MDC 15 to consider if restructuring the current MS–DRGs would better recognize the clinical distinctions of these patient populations. Any proposed modifications to these MS–DRGs will be addressed in future rulemaking consistent with our annual process.

As noted earlier, we have started our examination of the GROUPER logic that would determine an assignment of cases to MS–DRGs in MDC 15. During this review we noted the logic for MS–DRG 795 (Normal Newborn) includes five diagnosis codes from ICD–10–CM category Q81 (Epidermolysis bullosa). We refer the reader to the ICD–10 MS–DRG Version 41.1 Definitions Manual (available via on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software)* for complete documentation of the GROUPER logic for MS–DRG 795. The five diagnosis codes and their current MDC and MS–DRG assignments are listed in the following table.

ICD-10-CM Code	Description	MDC	MS-DRG
Q81.0	Epidermolysis bullosa simplex	09	606 and 607 (Minor Skin Disorders with MCC and without MCC, respectively)
Q81.1	Epidermolysis bullosa letalis		
Q81.2	Epidermolysis bullosa dystrophica		
Q81.8	Other epidermolysis bullosa		
Q81.9	Epidermolysis bullosa, unspecified	15	795 (Normal Newborn)

We reviewed this grouping issue and noted that epidermolysis bullosa (EB) is a group of genetic (inherited) disorders that causes skin to be fragile, blister, and tear easily in response to minimal friction or trauma. In some cases, blisters form inside the body in places such as the mouth, esophagus, other internal organs, or eyes. When the blisters heal, they can cause painful scarring. In severe cases, the blisters and scars can harm internal organs and tissue enough to be fatal. Patients diagnosed with severe cases of EB have a life expectancy that ranges from infancy to 30 years of age.

EB has four primary types: simplex, junctional, dystrophic, and Kindler syndrome, and within each type there are various subtypes, ranging from mild to severe. A skin biopsy can confirm a diagnosis of EB and identify which layers of the skin are affected and determine the type of epidermolysis bullosa. Genetic testing may also be ordered to diagnose the specific type and subtype of the disease. In caring for patients with EB, adaptions may be necessary in the form of handling, feeding, dressing, managing pain, and treating wounds caused by the blisters and tears. If there is a known diagnosis of EB, but the neonate has no physical signs at birth, there will still need to be specialty consultation in the inpatient setting or referral for outpatient follow-up. We believe the five diagnosis codes from ICD–10–CM category Q81 (Epidermolysis bullosa) describe conditions that require advanced care and resources similar to other conditions already assigned to the logic of MS–DRG 794 and MS–DRGs 595 and 596 (Major Skin Disorders with MCC and without MCC, respectively), even in cases where the type of EB is unspecified.

Therefore, for clinical consistency, we are proposing to reassign ICD–10–CM diagnosis codes Q81.0, Q81.1, Q81.2, Q81.8, and Q81.9 from MS–DRGs 606 and 607 in MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS–DRG 795 (Normal Newborn) in MDC 15 to MS–DRGs 595 and 596 in MDC 09 and MS–DRG 794 in MDC 15, effective October 1, 2024 for FY 2025.

9. MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Acute Leukemia

We identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs regarding the assignment of six ICD–10–CM diagnosis codes that describe a type of acute leukemia. Under the Version 32 ICD–9–CM based MS–DRGs, the ICD–9–CM diagnosis codes as shown in the following table were assigned to surgical MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), surgical MS–DRGs 823, 824, and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and without CC/MCC, respectively), and medical MS–DRGs 840, 841, and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms). The six ICD–10–PCS code translations also shown in the following table, that provide more detailed and specific information for the ICD–9–CM codes reflected, also currently group to MS–DRGs 820, 821, 822, 823, 824, 825, 840, 841 and 842 in the ICD–10 MS–DRGs Version 41.1. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/*

medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software) for complete documentation of the GROUPER logic for MS–DRGs 820, 821, 822, 823, 824, 825, 840, 841, and 842.

ICD-9-CM Diagnosis Code	Description	ICD-10-CM Diagnosis Code	Description
207.20	Megakaryocytic leukemia, without mention of having achieved remission	C94.20	Acute megakaryoblastic leukemia not having achieved remission
207.21	Megakaryocytic leukemia, in remission	C94.21	Acute megakaryoblastic leukemia, in remission
207.22	Megakaryocytic leukemia, in relapse	C94.22	Acute megakaryoblastic leukemia, in relapse
238.79	Other lymphatic and hematopoietic tissues	C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
238.79	Other lymphatic and hematopoietic tissues	C94.41	Acute panmyelosis with myelofibrosis, in remission
238.79	Other lymphatic and hematopoietic tissues	C94.42	Acute panmyelosis with myelofibrosis, in relapse

During our review of this issue, we noted that under ICD–9–CM, the diagnosis codes as reflected in the table did not describe the acuity of the diagnosis (for example, acute versus chronic). This is in contrast to their six comparable ICD–10–CM code translations listed in the previous table that provide more detailed and specific information for the ICD–9–CM diagnosis codes and do specify the acuity of the diagnoses.

We note that ICD–10–CM codes C94.20, C94.21, and C94.22 describe acute megakaryoblastic leukemia (AMKL), a rare subtype of acute myeloid leukemia (AML) that affects megakaryocytes, platelet-producing cells that reside in the bone marrow. Similarly, ICD–10–CM codes C94.40, C94.41, and C94.42 describe acute panmyelosis with myelofibrosis (APMF), a rare form of acute myeloid leukemia characterized by acute panmyeloid proliferation with increased blasts and accompanying fibrosis of the bone marrow that does not meet the criteria for AML with myelodysplasia related changes. As previously mentioned, these six diagnosis codes are assigned to MS–DRGs 820, 821, 822, 823, 824, 825, 840, 841, and 842. The GROUPER logic lists for MS–DRGs 820, 821, and 822 includes diagnosis codes describing lymphoma and both acute and non-acute leukemias, however the logic lists for MS–DRGs 823, 824, 825, 840, 841, and 842 contain diagnosis codes describing lymphoma and non-acute leukemias. In our analysis of this grouping issue, we also noted that cases reporting a chemotherapy principal diagnosis with a secondary diagnosis describing acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis are assigned to MS–DRGs 846, 847, and 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis, with MCC, with CC, and without CC/MCC, respectively) in Version 41.1.

Next, we examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRG 823, 824, 825, 840, 841, and 842 to identify cases reporting one of the six diagnosis codes listed previously that describe acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis. We also examined MS–DRGs 846, 847, and 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis, with MCC, with CC, and without CC/MCC, respectively). Our findings are shown in the following tables:

MS-DRGs 823, 824, and 825: All Cases and Cases Reporting Diagnosis Codes Describing Acute Megakaryoblastic Leukemia or Acute Panmyelosis with Myelofibrosis

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
823	All cases	2,235	14	$40,587
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	2	31.5	$49,600
824	All cases	1,764	6.8	$19,262
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	0	0	$0
825	All Cases	427	2.9	$10,959
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	1	6	$17,293

As shown in the table, in MS–DRG 823, we identified a total of 2,235 cases with an average length of stay of 14 days and average costs of $40,587. Of those 2,235 cases, there were two cases reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, with average costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 823 ($49,600 compared to $40,587) and a longer average length of stay (31.5 days compared to 14 days). We found zero cases in MS–DRG 824 reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis. In MS–DRG 825, we identified a total of 427 cases with an average length of stay of 2.9 days and average costs of $10,959. Of those 427 cases, there was one case reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, with costs higher than the average costs in the FY 2023 MedPAR file for MS–DRG 825 ($17,293 compared to $10,959) and a longer length of stay (6 days compared to 2.9 days).

MS-DRGs 840, 841, and 842: All Cases and Cases Reporting Diagnosis Codes Describing Acute Megakaryoblastic Leukemia or Acute Panmyelosis with Myelofibrosis				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
840	All cases	7,747	9.6	$26,215
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	12	8.7	$21,357
841	All cases	5,019	5.3	$13,502
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	6	2.8	$6,976
842	All Cases	726	3.4	$9,272
	Cases with C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	0	0	$0

As shown in the table, in MS–DRG 840, we identified a total of 7,747 cases with an average length of stay of 9.6 days and average costs of $26,215. Of those 7,747 cases, there were 12 cases reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 840 ($21,357 compared to $26,215) and a shorter average length of stay (8.7 days compared to 9.6 days). In MS–DRG 841, we identified a total of 5,019 cases with an average length of stay of 5.3 days and average costs of $13,502. Of those 5,019 cases, there were six cases reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 841 ($6,976 compared to $13,502) and a shorter average length of stay (2.8 days compared to 5.3 days). We found zero cases in MS–DRG 842 reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis.

MS-DRGs 846, 847, and 848: All Cases and Cases with a Chemotherapy Principal Diagnosis Code and a Secondary Diagnosis Code Describing Acute Megakaryoblastic Leukemia or Acute Panmyelosis with Myelofibrosis				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
846	All cases	2,936	8	$22,705
	Cases with a chemotherapy principal diagnosis code with a secondary diagnosis code of C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	0	0	$0
847	All cases	7,329	4.4	$11,250
	Cases with a chemotherapy principal diagnosis code with a secondary diagnosis code of C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	2	5	$7,569
848	All Cases	113	3.1	$7,347
	Cases with a chemotherapy principal diagnosis code with a secondary diagnosis code of C94.20, C94.21, C94.22, C94.40, C94.41, or C94.42	0	0	$0

As shown in the table, in MS–DRG 847, we identified a total of 7,329 cases with an average length of stay of 4.4 days and average costs of $11,250. Of those 7,329 cases, there were two cases reporting a chemotherapy principal diagnosis code with a secondary diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, with average costs lower than the average costs in the FY 2023 MedPAR file for MS–DRG 840 ($7,569 compared to $11,250) and a longer average length of stay (5 days compared to 4.4 days). We found zero cases in MS–DRGs 846 and 848 reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis.

Next, we examined the MS–DRGs within MDC 17. Given that the six diagnoses codes describe subtypes of acute myeloid leukemia, we determined that the cases reporting a principal diagnosis of acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis would more suitably group to medical MS–DRGs 834, 835, and 836 (Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). Similarly, cases reporting a chemotherapy principal diagnosis with a secondary diagnosis describing acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis would more suitably group to medical MS–DRGs 837, 838, and 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis, or with High Dose Chemotherapy Agent with MCC, with CC or High Dose Chemotherapy Agent, and without CC/MCC, respectively).

We then examined claims data from the September 2023 update of the FY 2023 MedPAR for MS–DRGs 834, 835, 836, 837, 838, and 839. Our findings are shown in the following table.

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
834	Acute Leukemia without Major O.R. Procedures with MCC	4,094	16.3	$49,986
835	Acute Leukemia without Major O.R. Procedures with CC	1,682	7.2	$19,023
836	Acute Leukemia without Major O.R. Procedures without CC/MCC	230	4	$11,225
837	Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC	1,567	15.3	$43,195
838	Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent	1,131	6.7	$18,162
839	Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC	502	4.4	$12,417

While the average costs for all cases in MS–DRGs 834, 835, 836, 837, 838, and 839 are higher than the average costs of the small number of cases reporting a diagnosis code that describes acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, or reporting a chemotherapy principal diagnosis with a secondary diagnosis describing acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis, and the average lengths of stay are longer, we note that diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 describe types of acute leukemia. For clinical coherence, we believe these six diagnosis codes would be more appropriately grouped along with other ICD–10–CM diagnosis codes that describe types of acute leukemia.

We reviewed this grouping issue, and our analysis indicates that the six diagnosis codes describing the acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis were initially assigned to the list of diagnoses in the GROUPER logic for MS–DRGs 823, 824, 825, 840, 841, and 842 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs. We also note that diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 do not describe non-acute leukemia diagnoses.

Accordingly, because the six diagnosis codes that describe acute megakaryoblastic leukemia or acute panmyelosis with myelofibrosis are not clinically consistent with non-acute leukemia diagnoses, and it is clinically appropriate to reassign these diagnosis codes to be consistent with the other diagnosis codes that describe acute leukemias in MS–DRGs 834, 835, 836, 837, 838, and 839, we are proposing the reassignment of diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 from MS–DRGs 823, 824 and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 840, 841, and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 834, 835, and 836 (Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 837, 838, and 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis, or with High Dose Chemotherapy Agent with MCC, with CC or High Dose Chemotherapy Agent, and without CC/MCC, respectively) in MDC 17, effective FY 2025. Under this proposal, diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 will continue to be assigned to surgical MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

In our review of the MS–DRGs in MDC 17 for further refinement, we next examined the procedures currently assigned to MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We note that the logic for case assignment to MS–DRGs 820, 821, 822, 826, 827, and 828 is comprised of a logic list entitled ''Operating Room Procedures'' which is defined by a list of 4,320 ICD–10–PCS procedure codes, including 90 ICD–10–PCS codes describing bypass procedures from the cerebral ventricle to various body parts. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 41.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps)* for complete documentation of the GROUPER logic for MS–DRGs 820, 821, 822, 826, 827, and 828.

In our review of the procedures currently assigned to MS–DRGs 820, 821, 822, 826, 827, and 828, we noted 12 ICD–10–PCS procedure codes that describe bypass procedures from the cerebral ventricle to the subgaleal space or cerebral cisterns, such as subgaleal or cisternal shunt placement, that are not included in the logic for MS–DRGs 820, 821, 822, 826, 827, and 828. The 12 procedure codes are listed in the following table.

ICD-10-PCS Code	Description
001607A	Bypass cerebral ventricle to subgaleal space with autologous tissue substitute, open approach
00160JA	Bypass cerebral ventricle to subgaleal space with synthetic substitute, open approach
00160KA	Bypass cerebral ventricle to subgaleal space with nonautologous tissue substitute, open approach
00160ZB	Bypass cerebral ventricle to cerebral cisterns, open approach
001637A	Bypass cerebral ventricle to subgaleal space with autologous tissue substitute, percutaneous approach
00163JA	Bypass cerebral ventricle to subgaleal space with synthetic substitute, percutaneous approach
00163KA	Bypass cerebral ventricle to subgaleal space with nonautologous tissue substitute, percutaneous approach
00163ZB	Bypass cerebral ventricle to cerebral cisterns, percutaneous approach
001647A	Bypass cerebral ventricle to subgaleal space with autologous tissue substitute, percutaneous endoscopic approach
00164JA	Bypass cerebral ventricle to subgaleal space with synthetic substitute, percutaneous endoscopic approach
00164KA	Bypass cerebral ventricle to subgaleal space with nonautologous tissue substitute, percutaneous endoscopic approach
00164ZB	Bypass cerebral ventricle to cerebral cisterns, percutaneous endoscopic approach

A subgaleal shunt consists of a shunt tube with one end in the lateral ventricles while the other end is inserted into the subgaleal space of the scalp, while a ventriculo-cisternal shunt diverts the cerebrospinal fluid flow from one of the lateral ventricles, via a ventricular catheter, to the cisterna magna of the posterior fossa. Both procedures allow for the drainage of excess cerebrospinal fluid. Indications for ventriculosubgaleal or ventriculo-cisternal shunting include acute head trauma, subdural hematoma, hydrocephalus, and leptomeningeal disease (LMD) in malignancies such as breast cancer, lung cancer, melanoma, acute lymphocytic leukemia (ALL) and non-hodgkin's lymphoma (NHL).

Recognizing that acute lymphocytic leukemia (ALL) and non-hodgkin's lymphoma (NHL) are indications for ventriculosubgaleal or ventriculo-cisternal shunting, we support adding the 12 ICD–10–PCS codes identified in the table to MS–DRGs 820, 821, 822, 826, 827, and 828 in MDC 17 for consistency to align with the procedure codes listed in the definition of MS–DRGs 820, 821, 822, 826, 827, and 828 and also to permit proper case assignment when a principal diagnosis from MDC 17 is reported with one of the procedure codes in the table that describes bypass procedures from the cerebral ventricle to the subgaleal space or cerebral cisterns. Therefore, we are proposing to add the 12 procedure codes that describe bypass procedures from the cerebral ventricle to the subgaleal space or cerebral cisterns listed previously to MS–DRGs 820, 821, 822, 826, 827, and 828 in MDC 17 for FY 2025.

Lastly, in our analysis of the MS–DRGs in MDC 17 for further refinement, we noted that the logic for case assignment to medical MS–DRGs 834, 835, and 836 (Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) as displayed in the ICD–10 MS–DRG Version 41.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) is comprised of a logic list entitled ''Principal Diagnosis'' and is defined by a list of 27 ICD–10–CM diagnosis codes describing various types of acute leukemias. When any one of the 27 listed diagnosis codes from the ''Principal Diagnosis'' logic list is reported as a principal diagnosis, without a procedure code designated as an O.R. procedure or without a procedure code designated as a non-O.R. procedure that affects the MS–DRG, the case results in assignment to MS–DRG 834, 835, or 836 depending on the presence of any additional MCC or CC secondary diagnoses. We note however, that while not displayed in the ICD–10 MS–DRG Version 41.1 Definitions Manual, when any one of the 27 listed diagnosis codes from the ''Principal Diagnosis'' logic list is reported as a principal diagnosis, along with a procedure code designated as an O.R. procedure that is not listed in the logic list of MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), the case also results in assignment to medical MS–DRG 834, 835, or 836 depending on the presence of any additional MCC or CC secondary diagnoses.

As medical MS–DRG 834, 835, and 836 contains GROUPER logic that includes ICD–10–PCS procedure codes designated as O.R. procedures, we examined claims data from the September 2023 update of the FY 2023 MedPAR file for MS–DRG 834, 835, and 836 to identify cases reporting an O.R. procedure. Our findings are shown in the following table:

MS-DRGs 834, 835, and 836: All Cases and Cases Reporting an O.R. Procedure

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
834	All cases	4,094	16.3	$49,986
	Cases reporting an O.R. procedure	277	28.2	$92,246
835	All cases	1,682	7.2	$19,023
	Cases reporting an O.R. procedure	79	10.4	$30,771
836	All Cases	230	4	$11,225
	Cases reporting an O.R. procedure	7	5.9	$17,950

As shown by the table, in MS–DRG 834, we identified a total of 4,094 cases, with an average length of stay of 16.3 days and average costs of $49,986. Of those 4,094 cases, there were 277 cases reporting an O.R. procedure, with higher average costs as compared to all cases in MS–DRG 834 ($92,246 compared to $49,986), and a longer average length of stay (28.2 days compared to 16.3 days). In MS–DRG 835, we identified a total of 1,682 cases with an average length of stay of 7.2 days and average costs of $19,023. Of those 1,682 cases, there were 79 cases reporting an O.R. procedure, with higher average costs as compared to all cases in MS–DRG 835 ($30,771 compared to $19,023), and a longer average length of stay (10.4 days compared to 7.2 days). In MS–DRG 836, we identified a total of 230 cases with an average length of stay of 4 days and average costs of $11,225. Of those 230 cases, there were 7 cases reporting an O.R. procedure, with higher average costs as compared to all cases in MS–DRG 836 ($17,950 compared to $11,225), and a longer average length of stay (5.9 days compared to 4 days). The data analysis shows that the average costs of cases reporting an O.R. procedure are higher than for all cases in their respective MS–DRG.

The data analysis clearly shows that cases reporting a principal diagnosis code describing a type of acute leukemia with an ICD–10–PCS procedure code designated as O.R. procedure that is not listed in the logic list of MS–DRGs 820, 821, and 822 have higher average costs and longer lengths of stay compared to all the cases in their assigned MS–DRG. For these reasons, we are proposing to create a new surgical MS–DRG for cases reporting a principal diagnosis code describing a type of acute leukemia with an O.R. procedure.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the claims data from the September 2023 update of the FY 2023 MedPAR file. The following table illustrates our findings for all 367 cases reporting a principal diagnosis code describing a type of acute leukemia with an ICD–10–PCS procedure code designated as O.R. procedure that is not listed in the logic list of MS–DRGs 820, 821, and 822. We believe the resulting proposed MS–DRG assignment, reflecting these modifications, is more

clinically homogeneous, coherent and better reflects hospital resource use.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Acute Leukemia with Other Procedures	367	23.9	$76,996

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of this FY 2025 IPPS/LTCH PPS proposed rule. As shown in the table, we identified a total of 367 cases using the claims data from the September 2023 update of the FY 2023 MedPAR file, so the criterion that there are at least 500 or more cases in each subgroup could not be met. Therefore, for FY 2025, we are not proposing to subdivide the proposed new MS DRG for acute leukemia with other procedures into severity levels.

In summary, for FY 2025, we are proposing to create a new base surgical MS–DRG for cases reporting a principal diagnosis describing a type of acute leukemia with an ICD–10–PCS procedure code designated as O.R. procedure that is not listed in the logic list of MS–DRGs 820, 821, and 822 in MDC 17. The proposed new MS–DRG is proposed new MS–DRG 850 (Acute Leukemia with Other Procedures). We are proposing to add the 27 ICD–10–CM diagnosis codes describing various types of acute leukemias currently listed in the logic list entitled ''Principal Diagnosis'' in MS–DRGs 834, 835, and 836 as well as ICD–10–CM codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 discussed earlier in this section to the proposed new MS–DRG 850. We are also proposing to add the procedure codes from current MS–DRGs 823, 824, and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and without CC/MCC, respectively) to the proposed new MS–DRG 850. We note that in the current logic list of MS–DRGs 823, 824, and 825 there are 189 procedure codes describing stereotactic radiosurgery of various body parts that are designated as non-O.R. procedures affecting the MS–DRG, therefore, as part of the logic for new MS–DRG 850, we are also proposing to designate these 189 codes as non-O.R. procedures affecting the MS–DRG.

In addition, we are proposing to revise the titles for MS–DRGs 834, 835, and 836 by deleting the reference to ''Major O.R. Procedures'' in the title. Specifically, we are proposing to revise the titles of medical MS–DRGs 834, 835, and 836 from ''Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC'', respectively to ''Acute Leukemia with MCC, with CC, and without CC/MCC'', respectively to better reflect the GROUPER logic that will no longer include ICD–10–PCS procedure codes designated as O.R. procedures. We note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.C.15. of this proposed rule.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of our review of the claims data from the September 2023 update of the FY 2023 MedPAR file of cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we did not identify any cases for reassignment and are not proposing to move any cases from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into a surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

In addition to the internal review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned. We did not receive any requests suggesting reassignment.

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS DRGs to the other group of MS DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Additionally, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. Based on the results of our review of the claims data from the September 2023 update of the FY 2023 MedPAR file we did not identify any cases for reassignment. We also did not receive any requests suggesting reassignment. Therefore, for FY 2025 we are not proposing to move any cases reporting procedure codes from MS–

DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

11. Operating Room (O.R.) and Non-O.R. Procedures

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed.

Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as

O.R. procedures or non-O.R. procedures affecting the MS–DRG, we recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.C.13 of the preamble of this proposed rule, we are making Table 6B.—New Procedure Codes—FY 2025 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html.* We also refer readers to the ICD–10 MS–DRG Version 41.1 Definitions Manual at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We stated we plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. We also stated that in consideration of the PHE, we believed it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review.

We stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58749) that we continue to believe additional time is necessary as we continue to develop our process and methodology. Therefore, we stated we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking. In response to this discussion in the FY 2024 IPPS/LTCH PPS final rule, we received a comment by the October 20, 2023 deadline. The commenter acknowledged that there is no easy rule that would allow CMS to designate certain surgeries as ''non-O.R.'' procedures. The commenter stated that they believed that open procedures should always be designated O.R. procedures and approaches other than open should not be a sole factor in designating a procedure as non-O.R. as some minimally-invasive procedures using a percutaneous endoscopic approach require more training,

specialized equipment, time, and resources than traditional open procedures. In addition, the commenter stated that whether a procedure is frequently or generally performed in the outpatient setting should not be used for determination of O.R. vs non-O.R. designation and noted that a surgery that can be performed in the outpatient setting for a clinically stable patient may not be able to be safely performed on a patient who is clinically unstable. The commenter also asserted that for procedures that can be performed in various locations within the hospital, that is, bedside vs operating room, there should be a mechanism to differentiate the setting of the procedure to determine the MS–DRG assignment as in the commenter's assessment, the ICD–10 classification does not provide a way to indicate the severity of certain conditions, or the complexity of procedures performed.

CMS appreciates the commenter's feedback and recommendations as to factors to consider in evaluating O.R. designations. We agree with the commenter and believe that there may be other factors to consider with regard to resource utilization. As discussed in the FY 2024 IPPS/LTCH PPS final rule, we have signaled in prior rulemaking that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we will consider as we examine the designation of a procedure in the ICD–10–PCS classification system. We are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. We are considering the feedback received on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system as continue to develop our process and methodology, and will provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking. We encourage the public to continue to submit comments on any other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs for consideration.

For this FY 2025 IPPS/LTCH PPS proposed rule, we did not receive any requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures by the October 20, 2023 deadline. In this section of the proposed rule, we discuss the proposals we are making based on our internal review and analysis and we discuss the process that was utilized for evaluating each procedure code. For each procedure, we considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a non-extensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of this proposed rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended.

For procedures that would not typically require the resources of an operating room, we determined if the procedure should affect the MS–DRG assignment. In cases where we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, we did not specifically address that aspect in summarizing the proposals we are making based on our internal review and analysis in this section of this proposed rule.

b. Non-O.R. Procedures to O.R. Procedures

(1) Laparoscopic Biopsy of Intestinal Body Parts

During our review, we noted inconsistencies in how procedures involving laparoscopic excisions of intestinal body parts are designated. Procedure codes describing the laparoscopic excision of intestinal body parts differ by qualifier. ICD–10–PCS procedure codes describing excisions of intestinal body parts with the diagnostic qualifier ''X'', are used to report these procedures when performed for diagnostic purposes. We identified the following five related codes:

ICD-10-PCS Code	Description
0DBF4ZX	Excision of right large intestine, percutaneous endoscopic approach, diagnostic
0DBG4ZX	Excision of left large intestine, percutaneous endoscopic approach, diagnostic
0DBL4ZX	Excision of transverse colon, percutaneous endoscopic approach, diagnostic
0DBM4ZX	Excision of descending colon, percutaneous endoscopic approach, diagnostic
0DBN4ZX	Excision of sigmoid colon, percutaneous endoscopic approach, diagnostic

We noted the ICD–10–PCS procedure codes describing the laparoscopic excision of intestinal body parts for diagnostic purposes listed previously have been assigned different attributes in terms of designation as an O.R. or Non-O.R. procedure when compared to similar procedures describing the laparoscopic excisions of intestinal body parts for nondiagnostic purposes. In the ICD–10 MS–DRGs Version 41, these ICD–10–PCS codes are currently recognized as non-O.R. procedures for purposes of MS–DRG assignment, while similar excision of intestinal body part procedure codes with the same approach but different qualifiers are recognized as O.R. procedures.

Upon further review and consideration, we believe that procedure codes 0DBF4ZX, 0DBG4ZX, 0DBL4ZX, 0DBM4ZX and 0DBN4ZX describing a laparoscopic excision of an intestinal body parts for diagnostic

purposes warrant designation as an O.R. procedures consistent with other laparoscopic excision procedures performed on the same intestinal body parts for nondiagnostic purposes. We also believe it is clinically appropriate for these procedures to group to the same MS–DRGs as the procedures describing excision procedures performed on the intestinal body parts for nondiagnostic purposes. Therefore, we are proposing to add procedure codes 0DBF4ZX, 0DBG4ZX, 0DBL4ZX, 0DBM4ZX and 0DBN4ZX to the FY 2025 ICD–10 MS–DRG Version 42 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, CC, without CC/MCC, respectively) and MS–DRGS 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

(2) Laparoscopic Biopsy of Gallbladder and Pancreas

During our review, we noted inconsistencies in how procedures involving laparoscopic excisions of gallbladder or pancreas are designated. Procedure codes describing the laparoscopic excision of the gallbladder or pancreas differ by qualifier. The ICD–10–PCS procedure code describing an excision of the gallbladder and the procedure code describing an excision of the pancreas with the diagnostic qualifier ''X'', are used to report these procedures when performed for diagnostic purposes. We identified the following two related codes:

ICD-10-PCS Code	Description
0FB44ZX	Excision of gallbladder, percutaneous endoscopic approach, diagnostic
0FBG4ZX	Excision of pancreas, percutaneous endoscopic approach, diagnostic

We noted the ICD–10–PCS procedure codes describing the laparoscopic excision of the gallbladder or the pancreas for diagnostic purposes listed previously have been assigned different attributes in terms of designation as an O.R. or a Non-O.R. procedure when compared to similar procedures describing the laparoscopic excisions of the gallbladder or the pancreas for nondiagnostic purposes. In the ICD–10 MS–DRGs Version 41, these ICD–10–PCS codes are currently recognized as non-O.R. procedures for purposes of MS–DRG assignment, while similar excision of the gallbladder or the pancreas procedure codes with the same approach but different qualifiers are recognized as O.R. procedures.

Upon further review and consideration, we believe that procedure code 0FB44ZX describing a laparoscopic excision of the gallbladder for diagnostic purposes and procedure code 0FBG4ZX describing a laparoscopic excision of the pancreas for diagnostic purposes both warrant designation as an O.R. procedure consistent with other laparoscopic excision procedures performed on the same body parts for nondiagnostic purposes. We also believe it is clinically appropriate for these procedures to group to the same MS–DRGs as the procedures describing excision procedures performed on the gallbladder or pancreas for nondiagnostic purposes. Therefore, we are proposing to add procedure code 0FB44ZX to the FY 2025 ICD–10 MS–DRG Version 42 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 411, 412, and 413 (Cholecystectomy with C.D.E., with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 417, 418, and 419 (Laparoscopic Cholecystectomy without C.D.E., with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS–DRGS 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

We are also proposing to add procedure code 0FBG4ZX to the FY 2025 ICD–10 MS–DRG Version 42 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 405, 406, and 407 (Pancreas, Liver and Shunt Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 628, 629 and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

12. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2025

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal

diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 IPPS/LTCH PPS final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater

number of caregivers, additional testing, intensive care unit care, extended length of stay).

- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete summation of the comments we received for each of the nine guiding principles and our responses to those comments. We note that since the FY 2021 IPPS/LTCH PPS final rule we have continued to solicit feedback regarding the nine guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We have encouraged the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code when providing feedback or comments. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26748 through 26750) we illustrated how the nine guiding principles might be applied in evaluating changes to the severity designations of diagnosis codes in our discussion of our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness. Since the FY 2021 IPPS/LTCH PPS final rule, we have not received any additional feedback or comments on the nine guiding principles; therefore, we are proposing to finalize the nine guiding principles as listed previously in this FY 2025 IPPS/LTCH PPS proposed rule. Under this proposal, our evaluations to determine the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of the nine guiding principles.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), we stated that as the new unspecified edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we also requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [4] we stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

We noted that social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[5] The subset of Z codes that describe the social determinants of health are found in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances). These codes describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation.

We received numerous public comments that expressed a variety of views on our comment solicitation, including many comments that were supportive, and others that offered specific suggestions for our consideration in future rulemaking. Many commenters applauded CMS' efforts to encourage documentation and reporting of SDOH diagnosis codes given the impact that social risks can have on health outcomes. These commenters stated that it is critical that physicians, other health care professionals, and facilities recognize the impact SDOH have on the health of their patients. Many commenters also stated that the most immediate and important action CMS could take to increase the use of SDOH Z codes is to finalize the evidence-based ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures proposed to be adopted in the Hospital Inpatient Quality Reporting (IQR) Program. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49202 through 49220), CMS finalized the ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures in the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48867 through 48872) for the complete discussion of the public comments received regarding the request for information on SDOH diagnosis codes.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), based on our analysis of the impact on resource use for the ICD–10–CM Z codes that describe homelessness and after consideration of public comments, we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. We stated our expectation that finalizing the changes would encourage the increased documentation and reporting of the diagnosis codes describing social and economic circumstances and serve as an example for providers that, when they document and report SDOH codes, CMS can further examine the claims data and consider future changes to the designation of these codes when reported as a secondary diagnosis. We further stated CMS would continue to monitor and evaluate the reporting of the diagnosis codes describing social and economic circumstances.

We refer the reader to the following section of this proposed rule for our proposed changes to the severity level designation for the diagnosis codes that describe inadequate housing and housing instability for FY 2025.

We have updated the Impact on Resource Use Files on the CMS website so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2023 MedPAR files. These files are posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* As discussed in prior rulemaking, we also continue to be interested in receiving feedback on how we might further foster the documentation and reporting of the

[4] *Available at: https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[5] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

For new diagnosis codes approved for FY 2025, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.C.13 of this proposed rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2025.

c. Proposed Changes to Severity Levels

1. SDOH—Inadequate Housing/Housing Instability

As discussed earlier in this section, in continuation of our examination of the SDOH Z codes, for this proposed rule, we reviewed the mathematical data on the impact on resource use for the subset of ICD–10–CM Z codes that describe the social determinants of health found in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances).

The ICD–10–CM SDOH Z codes that describe inadequate housing and housing instability are currently designated as NonCCs when reported as secondary diagnoses. The following table reflects the impact on resource use data generated using claims from the September 2023 update of the FY 2023 MedPAR file. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and a more detailed explanation of the columns in the table.

ICD-10-CM Code[a]	Description[b]	Total Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
Z59.10	Inadequate housing, unspecified	227	21	2.63	85	1.38	121	2.81
Z59.11	Inadequate housing environmental temperature	74	4	0.51	33	1.02	37	2.64
Z59.12	Inadequate housing utilities	162	12	0.99	80	1.65	70	2.39
Z59.19	Other inadequate housing	987	93	1.85	431	2.82	463	3.07
Z59.811	Housing instability, housed, with risk of homelessness	165	21	1.97	79	2.51	65	3.18
Z59.812	Housing instability, housed, homelessness in past 12 months	141	15	0.76	65	1.77	61	2.33
Z59.819	Housing instability, housed unspecified	1,237	96	0.92	619	2.25	522	2.88

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

The table shows that the C1 value is 2.63 for ICD–10–CM diagnosis code Z59.10 and 1.85 for ICD–10–CM diagnosis code Z59.19. A value close to 2.0 in column C1 suggests that the secondary diagnosis is more aligned with a CC than a NonCC. Because the C1 values in the table are generally close to 2, the data suggest that when these two SDOH Z codes are reported as a secondary diagnosis, the resources involved in caring for a patient experiencing inadequate housing support increasing the severity level from a NonCC to a CC. In contrast, the C1 value for ICD–10–CM diagnosis code Z59.11 is 0.51 and is 0.99 for ICD–10–CM diagnosis code Z59.12. A C1 value generally closer to 1 suggests the resources involved in caring for patients experiencing inadequate housing in terms of environmental temperature and utilities are more aligned with a NonCC severity level than a CC or an MCC severity level.

The underlying cause of the inconsistency between the C1 values for inadequate housing, unspecified and other inadequate housing and the two more specific codes that describe the necessities unavailable in the housing environment is unclear. We note that diagnosis codes Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), and Z59.19 (Other inadequate housing) became effective on April 1, 2023 (FY 2023). In reviewing the historical C1 values for code Z59.1 (Inadequate housing), the predecessor code before the code was expanded to further describe inadequate housing and the basic necessities unavailable in the housing environment, we note the mathematical data for the impact on resource use generated using claims from the FY 2019, FY 2020, FY 2021, and FY 2022 MedPAR files reflects C1 values for code Z59.1 of 2.09, 1.73, 2.04, and 2.69, respectively. We refer the reader to the Impact on Resource Use Files generated using claims from the FY 2019 through the FY 2022 MedPAR files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* We believe the lower C1 values for ICD–10–CM

codes Z59.11 (Inadequate housing environmental temperature) and Z59.12 (Inadequate housing utilities) reflected in the mathematical data for the impact on resource use generated using claims from the FY 2023 MedPAR file may be attributed to lack of use or knowledge about the newly expanded codes, such that the data may not yet reflect the full impact on resource use for patients experiencing these circumstances.

Similarly, the table shows that the C1 value is 1.97 for ICD–10–CM diagnosis code Z59.811. A value close to 2.0 in column C1 suggests that the secondary diagnosis is more aligned with a CC than a NonCC. Because the C1 value in the table is generally close to 2, the data suggest that when this SDOH Z code is reported as a secondary diagnosis, the resources involved in caring for a patient experiencing an imminent risk of homelessness support increasing the severity level from a NonCC to a CC. In contrast, the C1 value for ICD–10–CM diagnosis code Z59.812 (Housing instability, housed, homelessness in past 12 months) and (Housing instability, housed unspecified) is 0.76 and is 0.92 for ICD–10–CM diagnosis code Z59.819. A C1 value generally closer to 1 suggests the resources involved in caring for patients experiencing housing instability, with history of homelessness in the past 12 months or housing instability, unspecified are more aligned with a NonCC severity level than a CC or an MCC severity level. The underlying cause of the inconsistency between the C1 values for codes describing housing instability is unclear.

We note that diagnosis codes Z59.811, Z59.812, and Z59.819 became effective on October 1, 2021 (FY 2022). In reviewing the historical C1 values for code Z59.8 (Other problems related to housing and economic circumstances), the predecessor code before the code was expanded to further describe the problems related to housing and economic circumstances, we note the mathematical data for the impact on resource use generated using claims from the FY 2019 and FY 2020 MedPAR files reflects C1 values for code Z59.8 of 1.92 and 1.63, respectively. There were no data reflected for this code in the Impact on Resource Use File generated using claims from the FY 2021 MedPAR files. The mathematical data for the impact on resource use generated using claims from the FY 2022 MedPAR file reflects C1 values for codes Z59.811, Z59.812, and Z59.819 of 2.44, 3.12, and 2.09, respectively. We are uncertain if the fluctuations in the C1 values from year to year, or FY 2021, in particular, may reflect fluctuations that may be a result of the COVID–19 public health emergency or even reduced hospitalizations of certain conditions. We are also uncertain if the fluctuations may be attributed to lack of use or knowledge about the expanded codes, such that the data on the reporting of codes Z59.812 and Z59.819 may not yet reflect the full impact on resource use for patients experiencing these circumstances.

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), following the listening session on October 8, 2019, we reconvened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts to identify guiding principles to apply in evaluating whether changes to the severity level designations of diagnoses are needed and to ensure the severity designations appropriately reflect resource use based on review of the claims data, as well as consideration of relevant clinical factors (for example, the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses) and improve the overall accuracy of the IPPS payments.

In considering the nine guiding principles identified by the workgroup, as summarized previously, we note that, similar to homelessness, inadequate housing and housing instability are circumstances that can impede patient cooperation or management of care, or both. In addition, patients experiencing inadequate housing and housing instability can require a higher level of care by needing an extended length of stay.

Inadequate housing is defined as an occupied housing unit that has moderate or severe physical problems (for example, deficiencies in plumbing, heating, electricity, hallways, and upkeep).[6] [7] Features of substandard housing have long been identified as contributing to the spread of infectious diseases. Patients living in inadequate housing may be exposed to health and safety risks, such as vermin, mold, water leaks, and inadequate heating or cooling systems.[8] [9] An increasing body of evidence has associated poor housing conditions with morbidity from infectious diseases, chronic illnesses, exposure to toxins, injuries, poor nutrition, and mental disorders.[10]

Housing instability encompasses a number of challenges, such as having trouble paying rent, overcrowding, moving frequently, or spending the bulk of household income on housing.[11] These experiences may negatively affect physical health and make it harder to access health care. Studies have found moderate evidence to suggest that housing instability is associated with higher prevalence of overweight/obesity, hypertension, diabetes, and cardiovascular disease, worse hypertension and diabetes control, and higher acute health care utilization among those with diabetes and cardiovascular disease.[12]

In reviewing the mathematical data for the impact on resource use generated using claims from the FY 2023 MedPAR file for the seven ICD–10–CM codes describing inadequate housing and housing instability comprehensively and reviewing the potential impact these circumstances could have on patients' clinical course, we note that whether the patient is experiencing inadequate housing or housing instability, the patient may have limited or no access to prescription medicines or over-the-counter medicines, including adequate locations to store medications away from the heat or cold, and have difficulties adhering to medication regimens. Experiencing inadequate housing or housing instability may negatively affect a patient's physical health and make it harder to access timely health care.[8,9] Delays in medical care may increase morbidity and mortality risk among those with underlying, preventable, and treatable medical conditions.[13] In

[6] US Bureau of the Census. American Housing Survey (AHS). Washington, DC: US Bureau of the Census; 2010. Available at *http://www.census.gov/hhes/www/housing/ahs/ahs.html.*

[7] US Bureau of the Census. Codebook for the American Housing Survey, public use file: 1997 and later. Washington, DC: US Bureau of the Census; 2009. Available at *http://www.huduser.org/portal/datasets/ahs/AHS_Codebook.pdf.*

[8] Hernández, D. (2016). Affording housing at the expense of health: Exploring the housing and neighborhood strategies of poor families. Journal of Family Issues, *37*(7), 921–946. doi: 10.1177/0192513X14530970.

[9] Joint Center for Housing Studies. (2020). The state of the nation's housing 2020. Harvard University. *https://www.jchs.harvard.edu/sites/default/files/reports/files/Harvard_JCHS_The_State_of_the_Nations_Housing_2020_Report_Revised_120720.pdf.*

[10] Krieger J, Higgins DL. Housing and health: time again for public health action. Am J Public Health. 2002 May;92(5):758–68. doi: 10.2105/ajph.92.5.758. PMID: 11988443; PMCID: PMC1447157.

[11] Office of Disease Prevention and Health Promotion. Retrieved on December 27, 2023 from *https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/housing-instability.*

[12] Gu, K.D., Faulkner, K.C. & Thorndike, A.N. Housing instability and cardiometabolic health in the United States: a narrative review of the literature. BMC Public Health 23, 931 (2023). *https://doi.org/10.1186/s12889-023-15875-6.*

[13] Gertz AH, Pollack CC, Schultheiss MD, Brownstein JS. Delayed medical care and underlying health in the United States during the COVID–19 pandemic: A cross-sectional study. Prev

addition, findings also suggest that patients experiencing inadequate housing or housing instability are associated with higher rates of inpatient admissions for mental, behavioral, and neurodevelopmental disorders, longer hospital stays, and substantial health care costs.[14]

Therefore, after considering the impact on resource use data generated using claims from the September 2023 update of the FY 2023 MedPAR file for the seven ICD–10–CM diagnosis codes that describe inadequate housing and housing instability and consideration of the nine guiding principles, we are proposing to change the severity level designation for diagnosis codes Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from NonCC to CC for FY 2025.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48868), if SDOH Z codes are not consistently reported in inpatient claims data, our methodology utilized to mathematically measure the impact on resource use, as described previously, may not adequately reflect what additional resources were expended by the hospital to address these SDOH circumstances in terms of requiring clinical evaluation, extended length of hospital stay, increased nursing care or monitoring or both, and comprehensive discharge planning. We will continue to monitor SDOH Z code reporting, including reporting based on SDOH screening performed as a result of new quality measures in the Hospital Inpatient Quality Reporting program. We may consider proposing changes for other SDOH codes in the future based on our analysis of the impact on resource use, per our methodology, as previously described, and consideration of the guiding principles. We also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

To inform future rulemaking, feedback and other suggestions may be submitted by October 20, 2024 and directed to MEARIS™ at: *https://mearis.cms.gov/public/home.*

2. Causally Specified Delirium

Additionally, for this FY 2025 IPPS/LTCH PPS proposed rule, we received a request to change the severity level designations of the ICD–10–CM diagnosis codes that describe causally specified delirium from CC to MCC when reported as secondary diagnoses. Causally specified delirium is delirium caused by the physiological effects of a medical condition, by the direct physiological effects of a substance or medication, including withdrawal, or by multiple or unknown etiological factors. The requestor noted that ICD–10–CM diagnosis codes G92.8 (Other toxic encephalopathy), G92.9 (Unspecified toxic encephalopathy) and G93.41 (Metabolic encephalopathy) are currently all designated as MCCs. According to the requestor, a diagnosis of delirium implies an underlying acute encephalopathy, and as such, the severity designation of the diagnosis codes that describe causally specified delirium should be on par with the severity designation of the diagnosis codes that describe toxic encephalopathy and metabolic encephalopathy. The requestor stated that toxic encephalopathy, metabolic encephalopathy, and causally specified delirium all describe core symptoms of impairment of level of consciousness and cognitive change caused by a medical condition or substance.

The requestor further stated that there is robust literature detailing the impact delirium can have on cognitive decline, rates of functional decline, subsequent dementia diagnosis, institutionalization, care complexity and costs, readmission rates, and mortality. The requestor considered each of the nine guiding principles discussed earlier in this section and noted how each of the principles could be applied in evaluating changes to the severity designations of the diagnosis codes that describe causally specified delirium in their request. Specifically, the requestor stated that delirium is a textbook example that maps to the nine guiding principles for evaluating a potential change in severity designation in that delirium (1) has a bidirectional link with dementia, (2) indexes physiological vulnerability across populations, (3) impacts healthcare systems across levels of care, (4) complicates postoperative recovery, (5) consigns patients to higher levels of care, and for longer, (6)impedes patient engagement in care, (7) has several recent treatment guidelines, (8) indicates neuronal/brain injury, and (9) represents a common expression of terminal illness.

The requestor identified 37 ICD–10–CM diagnosis codes that describe causally specified delirium. We agree that these 37 diagnosis codes are all currently designated as CCs. We refer the reader to Appendix G of the ICD–10 MS–DRG Version 41.1 Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the complete list of diagnoses designated as CCs when reported as secondary diagnoses, except when used in conjunction with the principal diagnosis in the corresponding CC Exclusion List in Appendix C. To evaluate this request, we analyzed the claims data in the September 2023 update of the FY 2023 MedPAR file. The following table shows the analysis for each of the diagnosis codes identified by the requestor that describe causally specified delirium.

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Med Rep. 2022 Aug;28:101882. doi: 10.1016/j.pmedr.2022.101882. Epub 2022 Jul 5. PMID: 35813398; PMCID: PMC9254505.

[14] Rollings KA, Kunnath N, Ryus CR, Janke AT, Ibrahim AM. Association of Coded Housing Instability and Hospitalization in the US. *JAMA Netw Open*. 2022;5(11):e2241951. doi:10.1001/jamanetworkopen.2022.41951.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
F05	Delirium due to known physiological condition	146,281	4,906	1.68	37,811	2.46	103,564	3.38
F10.121	Alcohol abuse with intoxication delirium	187	11	1.45	69	2.13	107	3.30
F10.131	Alcohol abuse with withdrawal delirium	833	25	1.26	186	2.67	622	3.34
F10.221	Alcohol dependence with intoxication delirium	298	10	0.98	88	2.62	200	3.42
F10.231	Alcohol dependence with withdrawal delirium	4,361	143	1.94	981	2.73	3,237	3.49
F10.921	Alcohol use, unspecified with intoxication delirium	21	1	1.21	8	2.99	12	2.56
F10.931	Alcohol use, unspecified with withdrawal delirium	153	6	0.75	43	2.80	104	3.18
F11.121	Opioid abuse with intoxication delirium	29	-	-	5	1.99	24	3.06
F11.221	Opioid dependence with intoxication delirium	42	1	4.00	11	2.34	30	3.13
F11.921	Opioid use, unspecified with intoxication delirium	173	16	2.14	76	2.34	81	2.94
F12.121	Cannabis abuse with intoxication delirium	14	-	-	2	2.45	12	2.24
F12.221	Cannabis dependence with intoxication delirium	1	-	-	1	0.99	-	-
F12.921	Cannabis use, unspecified with intoxication delirium	23	-	-	10	2.41	13	1.25
F13.121	Sedative, hypnotic or anxiolytic abuse with intoxication delirium	7	-	-	2	0.86	5	1.66
F13.131	Sedative, hypnotic or anxiolytic abuse with withdrawal delirium	15	-	-	10	3.09	5	2.82
F13.221	Sedative, hypnotic or anxiolytic dependence with intoxication delirium	15	-	-	8	1.90	7	3.01
F13.231	Sedative, hypnotic or anxiolytic dependence with withdrawal delirium	184	5	0.96	43	2.41	136	3.48
F13.921	Sedative, hypnotic or anxiolytic use, unspecified with intoxication delirium	58	3	0.77	14	0.87	41	3.19
F13.931	Sedative, hypnotic or anxiolytic use, unspecified with withdrawal delirium	43	1	1.51	16	2.29	26	3.21
F14.121	Cocaine abuse with intoxication with delirium	28	2	0.35	2	3.22	24	3.32
F14.221	Cocaine dependence with intoxication delirium	5	-	-	3	2.39	2	3.85
F14.921	Cocaine use, unspecified with intoxication delirium	6	-	-	2	0.77	4	2.56
F15.121	Other stimulant abuse with intoxication delirium	51	2	1.16	12	2.21	37	3.20
F15.221	Other stimulant dependence with intoxication delirium	10	-	-	2	0.28	8	3.02
F15.921	Other stimulant use, unspecified with intoxication delirium	16	1	1.97	3	0.68	12	2.42
F16.121	Hallucinogen abuse with intoxication with delirium	4	-	-	1	0.66	3	3.63
F16.221	Hallucinogen dependence with intoxication with delirium	-	-	-	-	-	-	-

F16.921	Hallucinogen use, unspecified with intoxication with delirium	1	1	0.98	-	-	-	-
F18.121	Inhalant abuse with intoxication delirium	-	-	-	-	-	-	-
F18.221	Inhalant dependence with intoxication delirium	-	-	-	-	-	-	-
F18.921	Inhalant use, unspecified with intoxication with delirium	-	-	-	-	-	-	-
F19.121	Other psychoactive substance abuse with intoxication delirium	27	-	-	9	2.47	18	3.55
F19.131	Other psychoactive substance abuse with withdrawal delirium	8	-	-	1	1.40	7	3.78
F19.221	Other psychoactive substance dependence with intoxication delirium	7	-	-	1	0.54	6	3.74
F19.231	Other psychoactive substance dependence with withdrawal delirium	53	2	2.16	21	2.75	30	3.44
F19.921	Other psychoactive substance use, unspecified with intoxication with delirium	312	19	1.00	126	2.41	167	3.31
F19.931	Other psychoactive substance use, unspecified with withdrawal delirium	28	-	-	10	2.95	18	3.39

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

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We analyzed these data as described in FY 2008 IPPS final rule (72 FR 47158 through 47161). The table shows that the C1 values of the diagnosis codes that describe causally specified delirium range from a low of 0.35 to a high of 4.00. As stated earlier, a C1 value close to 2.0 suggests the condition is more like a CC than a non-CC but not as significant in resource usage as an MCC. On average, the C1 values of the diagnoses that describe causally specified delirium suggest that these codes are more like a NonCC than a CC. We note diagnosis code F11.221 (Opioid dependence with intoxication delirium) had a C1 value of 4.00, however our analysis reflects that this diagnosis code was reported as a secondary diagnosis in only 42 claims, and only one claim reported F11.221 as a secondary diagnosis with no other secondary diagnosis or with all other secondary diagnoses that are NonCCs.

The C2 findings of the diagnosis codes that describe causally specified delirium range from a low of 0.28 to a high of 3.22 and the C3 findings range from a low of 1.25 to a high of 3.85. The data are clearly mixed between the C2 and C3 findings, and do not consistently support a change in the severity level. On average, the C2 and C3 findings again suggest that these codes that describe causally specified delirium are more similar to a NonCC.

In considering the nine guiding principles, as summarized previously, we note that delirium is a diagnosis that can impede patient cooperation or management of care or both. Delirium is a confusional state that can manifest as agitation, tremulousness, and hallucinations or even somnolence and decreased arousal. In addition, patients diagnosed with delirium can require a higher level of care by needing intensive monitoring, and a greater number of caregivers. Managing disruptive behavior, particularly agitation and combative behavior, is a challenging aspect in caring for patients diagnosed with delirium. Prevention and treatment of delirium can include avoiding factors known to cause or aggravate delirium; identifying and treating the underlying acute illness; and where appropriate using low-dose, short-acting pharmacologic agents.

After considering the C1, C2, and C3 values of the 37 ICD–10–CM diagnosis codes that describe causally specified delirium and consideration of the nine guiding principles, we believe these 37 codes should not be designated as MCCs. While there is a lack of consistent claims data to support a severity level change from CCs to MCCs, we recognize patients with delirium can utilize increased hospital resources and can be at a higher severity level. Therefore, we are proposing to retain the severity designation of the 37 codes listed previously as CCs for FY 2025.

d. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2025

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2025 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List–FY 2025;

Table 6J.1—Proposed Additions to the CC List–FY 2025; and

Table 6J.2—Proposed Deletions to the CC List–FY 2025

e. Proposed CC Exclusions List for FY 2025

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 41.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual (available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

Effective for the April 1, 2024 release of the ICD–10 MS–DRG Definitions Manual, Version 41.1, a new section has been added to Appendix C as follows:

Part 3: Secondary Diagnosis CC/MCC Severity Exclusions in Select MS–DRGs

Part 3 lists diagnosis codes that are designated as a complication or comorbidity (CC) or major complication or comorbidity (MCC) and included in the definition of the logic for the listed MS–DRGs. When reported as a secondary diagnosis and grouped to one of the listed MS–DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in DRG assignment.

The purpose of this new section is to include the list of MS–DRGs subject to what is referred to as suppression logic. In addition to the suppression logic excluding secondary diagnosis CC or MCC conditions that may be included in the definition of the logic for a DRG, it is also based on the presence of other secondary diagnosis logic defined within certain base DRGs. Therefore, if a MS–DRG has secondary diagnosis logic, the suppression is activated regardless of the severity of the secondary diagnosis code(s) for appropriate grouping and MS–DRG assignment.

Each MS–DRG is defined by a particular set of patient attributes including principal diagnosis, specific secondary diagnoses, procedures, sex, and discharge status. The patient attributes which define each MS–DRG are displayed in a series of headings which indicate the patient characteristics used to define the MS–DRG. These headings indicate how the patient's diagnoses and procedures are used in determining MS–DRG assignment. Following each heading is a complete list of all the ICD–10–CM diagnosis or ICD–10–PCS procedure codes included in the MS–DRG. One of these headings is secondary diagnosis.

- *Secondary diagnosis*. Indicates that a specific set of secondary diagnoses are used in the definition of the MS–DRG. For example, a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839.

The full list of MS–DRGs where suppression occurs is shown in the following table.

MS-DRG 008
MS-DRG 010
MS-DRG 019
*MS-DRGs 082-084
*MS-DRGs 177-179
*MS-DRGs 280-282
*MS-DRGs 283-285
*MS-DRGs 456-458
*MS-DRGs 582-583
MS-DRG 768
MS-DRG 790
MS-DRG 791
MS-DRG 792
MS-DRG 793
MS-DRG 794
*MS-DRGs 796-798
*MS-DRGs 805-807
*MS-DRGs 837-839
MS-DRG 927
*MS-DRGs 928-929
MS-DRG 933
MS-DRG 934
MS-DRG 935
MS-DRG 955
MS-DRG 956
*MS-DRGs 957-959
*MS-DRGs 963-965
*MS-DRGs 974-976
MS-DRG 977

* The MS-DRG(s) contain diagnoses that are specifically excluded from acting as a CC/MCC for severity in MS-DRG assignment.

We believe this additional information about the suppression logic may further assist users of the ICD–10 MS–DRG GROUPER software and related materials.

In our review of the MS–DRGs containing secondary diagnosis logic in association with the suppression logic previously discussed, we identified another set of MS–DRGs containing secondary diagnosis logic in the definition of the MS–DRG. Specifically, we identified MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), as displayed in the ICD–10 MS–DRG Version 41.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) which contains secondary diagnosis logic.

Of the seven logic lists included in the definition of MS–DRGs 673, 674, and 675, there are three ''Or Principal Diagnosis'' logic lists and one ''With Secondary Diagnosis'' logic list. The first ''Or Principal Diagnosis'' logic list is comprised of 21 diagnosis codes describing conditions such as chronic kidney disease, kidney failure, and complications related to a vascular dialysis catheter or kidney transplant. The second ''Or Principal Diagnosis'' logic list is comprised of four diagnosis codes describing diabetes with diabetic chronic kidney disease followed by a ''With Secondary Diagnosis'' logic list that includes diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). These logic lists are components of the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices. The third ''Or Principal Diagnosis'' logic list is comprised of three diagnosis codes describing Type 1 diabetes with different kidney complications as part of the special logic in MS–DRGs 673, 674, and 675 for pancreatic islet cell transplantation performed in the absence of any other surgical procedure.

Under the Version 41.1 ICD–10 MS–DRGs, diagnosis code N18.5 (Chronic kidney disease, stage 5) is currently designated as a CC and diagnosis code N18.6 (End stage renal disease) is designated as an MCC. In our review of the MS–DRGs containing secondary diagnosis logic in association with the suppression logic, we noted that currently, when some diagnosis codes from the ''Or Principal Diagnosis'' logic lists in MS–DRGs 673, 674, and 675 are reported as the principal diagnosis and either diagnosis code N18.5 or N18.6 from the ''With Secondary Diagnosis'' logic list is reported as a secondary diagnosis, some cases are grouping to MS–DRG 673 (Other Kidney and Urinary Tract Procedures with MCC) or to MS–DRG 674 (Other Kidney and Urinary Tract Procedures with CC) in the absence of any other MCC or CC secondary diagnoses being reported.

In our analysis of this issue, we noted that diagnosis codes N18.5 and N18.6 are excluded from acting as a CC or MCC, when reported with principal

diagnoses from Principal Diagnosis Collection Lists 1379 and 1380, respectively, as reflected in Part 1 of Appendix C in the CC Exclusion List. We refer the reader to Part 1 of Appendix C in the CC Exclusion List as displayed in the ICD–10 MS–DRG Version 41.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the complete list of principal diagnoses in Principal Diagnosis Collection Lists 1379 and 1380. Specifically, when codes N18.5 or N18.6 are reported as secondary diagnoses, they are considered as NonCCs when the diagnosis codes from the ''Or Principal Diagnosis'' logic lists in MS–DRGs 673, 674, and 675 reflected in the following table are reported as the principal diagnosis under the CC Exclusion logic.

Principal Diagnoses Codes in the "Or Principal Diagnosis" Logic List for MS-DRGs 673, 674, and 675 currently listed in Principal Diagnosis Collection List 1379 or 1380 in ICD-10 MS-DRG GROUPER Version 41

Principal Diagnosis ICD-10-CM Code	Description	PDX Collection Number
E09.22	Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease	1379: 294 codes 1380: 295 codes
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease	
N17.0	Acute kidney failure with tubular necrosis	
N17.1	Acute kidney failure with acute cortical necrosis	
N17.2	Acute kidney failure with medullary necrosis	
N17.8	Other acute kidney failure	
N17.9	Acute kidney failure, unspecified	
N18.5	Chronic kidney disease, stage 5	
N18.6	End stage renal disease	
N19	Unspecified kidney failure	

We also noted that currently, a subset of diagnosis codes from the first ''Or Principal Diagnosis'' logic list in MS–DRGs 673, 674, and 675 are not listed in Principal Diagnosis Collection Lists 1379 or 1380 for diagnosis codes N18.5 and N18.6, respectively. As a result, when one of the 13 diagnosis codes listed in the following table are reported as the principal diagnosis, and either diagnosis code N18.5 or N18.6 from the ''With Secondary Diagnosis'' logic list are reported as a secondary diagnosis, the cases are grouping to MS–DRG 673 (Other Kidney and Urinary Tract Procedures with MCC) or to MS–DRG 674 (Other Kidney and Urinary Tract Procedures with CC) when also reported with a procedure code describing the insertion of a tunneled or totally implantable vascular access device.

Principal Diagnoses Codes in the "Or Principal Diagnosis" Logic List for MS-DRGs 673, 674, and 675 not listed in Principal Diagnosis Collection List 1379 or 1380 in ICD-10 MS-DRG GROUPER Version 41	
Principal Diagnosis ICD-10-CM Code	**Description**
E88.3	Tumor lysis syndrome
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
R34	Anuria and oliguria
T79.5XXA	Traumatic anuria, initial encounter
T82.41XA	Breakdown (mechanical) of vascular dialysis catheter, initial encounter
T82.42XA	Displacement of vascular dialysis catheter, initial encounter
T82.43XA	Leakage of vascular dialysis catheter, initial encounter
T82.49XA	Other complication of vascular dialysis catheter, initial encounter
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant

Consistent with how other similar logic lists function in the ICD–10 GROUPER software for case assignment to the ''with MCC'' or ''with CC'' MS–DRGs, the logic for case assignment to MS–DRG 673 is intended to require any *other* diagnosis designated as an MCC and reported as a secondary diagnosis for appropriate assignment, and not the diagnoses currently listed in the logic for the definition of the MS–DRG. Likewise, the logic for case assignment to MS–DRG 674 is intended to require any *other* diagnosis designated as a CC and reported as a secondary diagnosis for appropriate assignment.

Therefore, for FY 2025, we are proposing to correct the logic for case assignment to MS–DRGs 673, 674, and 675 by adding suppression logic to exclude diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease) from the logic list entitled ''With Secondary Diagnosis'' from acting as a CC or an MCC, respectively, when reported as a secondary diagnosis with one of the 13 previously listed principal diagnosis codes from the ''Or Principal Diagnosis'' logic lists in MS–DRGs 673, 674, and 675 for appropriate grouping and MS–DRG assignment. Under this proposal, when diagnosis codes N18.5 or N18.6 are reported as a secondary diagnosis with one of the 13 previously listed principal diagnosis codes, the GROUPER will assign MS–DRG 675 (Other Kidney and Urinary Tract Procedures without CC/MCC) in the absence of any other MCC or CC secondary diagnoses being reported. We also note that the current list of MS–DRGs subject to suppression logic as previously discussed and listed under Version 41.1 includes MS–DRGs that are not subdivided by a two-way severity level split (''with MCC and without MCC'' or ''with CC/MCC and without CC/MCC'') or a three-way severity level split (with MCC, with CC, and without CC/MCC, respectively), or the listed MS–DRG includes diagnoses that are not currently designated as a CC or MCC. To avoid potential confusion, we are proposing to refine how the suppression logic is displayed under Appendix C—Part 3 to not display the MS–DRGs where the suppression logic has no impact on the grouping (meaning the logic list for the affected MS–DRG contains diagnoses that are all designated as NonCCs, or the MS–DRG is not subdivided by a severity level split) as reflected in the draft Version 42 ICD–10 MS–DRG Definitions Manual, which is available in association with this proposed rule at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

In addition, we are proposing changes to the ICD–10 MS–DRGs Version 42 CC Exclusion List based on the diagnosis code updates as discussed in section II.C.13. of this FY 2025 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2025; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2025; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2025; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2025. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal

diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

13. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2025, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. As discussed in section II.C.15. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2025;
- Table 6B.—New Procedure Codes—FY 2025;
- Table 6C.—Invalid Diagnosis Codes—FY 2025;
- Table 6D.—Invalid Procedure Codes—FY 2025;
- Table 6E.—Revised Diagnosis Code Titles—FY 2025;
- Table 6F.—Revised Procedure Code Titles—FY 2025;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2025;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2025;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2025;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2025;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2025;
- Table 6J.1.—Proposed Additions to the CC List—FY 2025; and
- Table 6J.2.—Proposed Deletions to the CC List—FY 2025.

14. Proposed Changes to the Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of

reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2025, as discussed in section II.C. of the preamble of this proposed rule, we are proposing to modify the existing surgical hierarchy for FY 2025 as follows.

As discussed in section II.C.4.a. of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for the MDC 05 (Diseases and Disorders of the Circulatory System) MS–DRGs as follows: In the MDC 05 MS–DRGs, we are proposing to sequence proposed new MS–DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation) above MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) and below MS–DRGs 231, 232, 233, 234, 235, and 236 (Coronary Bypass with or without PTCA, with or without Cardiac Catheterization or Open Ablation, with and without MCC, respectively). As discussed in section II.C.4.b. of the preamble of this proposed rule, we are proposing to revise the title for MS–DRG 276 from ''Cardiac Defibrillator Implant with MCC'' to ''Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator''.

As discussed in section II.C.6.b. of the preamble of this proposed rule, we are proposing to delete MS–DRGs 453, 454, and 455 (Combined Anterior and Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). Based on the changes we are proposing to make for those MS–DRGs in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), we are proposing to revise the surgical hierarchy for MDC 08 as follows: In MDC 08, we are proposing to sequence proposed new MS–DRGs 426, 427, and 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC, with CC, and without CC/MCC, respectively) above proposed new MS–DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical). We are proposing to sequence proposed new MS–DRGs 429 and 430 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC and without MCC, respectively) above MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) and below proposed new MS–DRG 402. We are proposing to sequence proposed new MS–DRGs 447 and 448 (Multiple Level Spinal Fusion Except Cervical with MCC and without MCC, respectively) above proposed revised MS–DRGs 459 and 460 (Single Level Spinal Fusion Except Cervical with and without MCC, respectively) and below MS–DRGs 456, 457, and 458.

Lastly, as discussed in section II.C.9. of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for the MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms) MS–DRGs as follows: For the MDC 17 MS–DRGs, we are proposing to sequence proposed new MS–DRG 850 (Acute Leukemia with Other Procedures) above MS–DRGs 823, 824 and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and without CC/MCC, respectively) and below MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 42 is illustrated in the following tables.

Proposed Surgical Hierarchy: MDC 05	
MS-DRG 215	Other Heart Assist System Implant
MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures
MS-DRGs 216-221	Cardiac Valve and Other Major Cardiothoracic Procedures
MS-DRGs 231-236	Coronary Bypass
Proposed New MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation
MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
Proposed New Title MS-DRG 276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
MS-DRG 277	Cardiac Defibrillator Implant without MCC
MS-DRGs 266-267	Endovascular Cardiac Valve Replacement and Supplement Procedures
MS-DRGs 268-269	Aortic and Heart Assist Procedures
MS-DRGs 228-229	Other Cardiothoracic Procedures
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures
MS-DRGs 270-272	Other Major Cardiovascular Procedures
MS-DRGs 239-241	Amputation for Circulatory System Disorders Except Upper Limb and Toe
MS-DRGs 242-244	Permanent Cardiac Pacemaker Implant
MS-DRG 245	AICD Generator Procedures
MS-DRG 265	AICD Lead Procedures
MS-DRGs 273-274	Percutaneous and Other Intracardiac Procedures
MS-DRGs 323-325	Coronary Intravascular Lithotripsy
MS-DRGs 321-322	Percutaneous Cardiovascular Procedures with Intraluminal Device
MS-DRGs 250-251	Percutaneous Cardiovascular Procedures without Intraluminal Device
MS-DRGs 278-279	Ultrasound Accelerated and Other Thrombolysis
MS-DRGs 252-254	Other Vascular Procedures
MS-DRGs 255-257	Upper Limb and Toe Amputation for Circulatory System Disorders
MS-DRGs 258-259	Cardiac Pacemaker Device Replacement
MS-DRGs 260-262	Cardiac Pacemaker Revision Except Device Replacement
MS-DRG 263	Vein Ligation and Stripping
MS-DRG 264	Other Circulatory O.R Procedures

Proposed Surgical Hierarchy: MDC 08	
Delete MS-DRGs 453-455	Combined Anterior and Posterior Spinal Fusion
Proposed New MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRGs 429-430	Combined Anterior and Posterior Cervical Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions
Proposed New MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical
Proposed New Title MS-DRGs 459-460	Single Level Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity
MS-DRGs 471-473	Cervical Spinal Fusion
MS-DRGs 474-476	Amputation for Musculoskeletal System and Connective Tissue Disorders
MS-DRGs 477-479	Biopsies of Musculoskeletal System and Connective Tissue
MS-DRGs 480-482	Hip and Femur Procedures Except Major Joint
MS-DRG 483	Major Joint or Limb Reattachment Procedures of Upper Extremities
MS-DRGs 485-489	Knee Procedures
MS-DRGs 518-520	Back and Neck Procedures Except Spinal Fusion
MS-DRGs 492-494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur
MS-DRGs 495-497	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur
MS-DRGs 498-499	Local Excision and Removal of Internal Fixation Devices of Hip and Femur
MS-DRGs 500-502	Soft Tissue Procedures
MS-DRGs 503-505	Foot Procedures
MS-DRG 506	Major Thumb or Joint Procedures
MS-DRGs 507-508	Major Shoulder or Elbow Joint Procedures
MS-DRG 509	Arthroscopy
MS-DRGs 510-512	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures
MS-DRGs 513-514	Hand or Wrist Procedures, Except Major Thumb or Joint Procedures
MS-DRGs 515-517	Other Musculoskeletal System and Connective Tissue O.R. Procedures

Proposed Surgical Hierarchy: MDC 17	
MS-DRGs 820-822	Lymphoma and Leukemia with Major O.R. Procedures
Proposed New MS-DRG 850	Acute Leukemia with Other Procedures
MS-DRGs 823-825	Lymphoma and Non-Acute Leukemia with Other Procedures
MS-DRGs 826-828	Myeloproliferative disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures
MS-DRGs 829-830	Myeloproliferative disorders or Poorly Differentiated Neoplasms with Other O.R. Procedures

15. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD- 10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-9-cm-diagnosis-procedure-codes-abbreviated-and-full-code-titles.*

The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health- related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and

proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2025 at a public meeting held on September 12–13, 2023 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2023.

The Committee held its Spring 2024 meeting on March 19–20, 2024. The deadline for submitting comments on these code proposals is April 19, 2024. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support, and for which complete tabular and indexing changes would be made by June 2024 would be included in the October 1, 2024 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this proposed rule, which are available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available on the CMS website as discussed in section VI. of the Addendum to the proposed rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 12–13, 2023 meeting and the March 19–20, 2024 meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.* The materials for the discussions relating to diagnosis codes at the September 12–13, 2023 meeting and March 19–20, 2024 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html.* These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov.*

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

CMS implemented 41 new procedure codes including the insertion of a palladium-103 collagen implant into the brain, the excision or resection of intestinal body parts using a laparoscopic hand-assisted approach, the transfer of omentum for pedicled omentoplasty procedures, and the administration of talquetamab into the ICD–10–PCS classification effective with discharges on and after April 1, 2024. The procedure codes are as follows:

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Procedure Code	Description	O.R.	MDC	MS-DRG
00H005Z	Insertion of radioactive element, palladium-103 collagen implant into brain, open approach	Y	01 01 21 24	023-024 025-027 907-909 955
02583ZF	Destruction of conduction mechanism using irreversible electroporation, percutaneous approach	Y	05	273-274
07TP4ZG	Resection of spleen, percutaneous endoscopic approach, hand-assisted	Y	05 06 08 16 17 17 21 24	264 356-358 515-517 799-801 820-822 826-828 907-909 957-959
097N0ZZ	Dilation of nasopharynx, open approach	Y	01 03 21 24	040-042 143-145 907-909 957-959
097N7ZZ	Dilation of nasopharynx, via natural or artificial opening	Y	01 03 21 24	040-042 143-145 907-909 957-959
097N8ZZ	Dilation of nasopharynx, via natural or artificial opening endoscopic	Y	01 03 21 24	040-042 143-145 907-909 957-959
0DBF4ZG	Excision of right large intestine, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17 21 24	264 329-331 628-630 820-822 826-828 907-909 957-959
0DBG4ZG	Excision of left large intestine, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17 21 24	264 329-331 628-630 820-822 826-828 907-909 957-959
0DBJ4ZG	Excision of appendix, percutaneous endoscopic approach, hand-assisted	Y	06	397-399
0DBL4ZG	Excision of transverse colon, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17 21 24	264 329-331 628-630 820-822 826-828 907-909 957-959
0DBM4ZG	Excision of descending colon, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17	264 329-331 628-630 820-822

			17 21 24	826-828 907-909 957-959
0DBN4ZG	Excision of sigmoid colon, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17 21 24	264 329-331 628-630 820-822 826-828 907-909 957-959
0DTF4ZG	Resection of right large intestine, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17 21 24	264 329-331 628-630 820-822 826-828 907-909 957-959
0DTG4ZG	Resection of left large intestine, percutaneous endoscopic approach, hand-assisted	Y	05 06 10 17 17	264 329-331 628-630 820-822 826-828 907-909 957-959
0DTJ4ZG	Resection of appendix, percutaneous endoscopic approach, hand-assisted	Y	05 06 13 21 24	264 397-399 749-750 907-909 957-959
0DTL4ZG	Resection of transverse colon, percutaneous endoscopic approach, hand-assisted	Y	05 06 17 17 21 24	264 329-331 820-822 826-828 907-909 957-959
0DTM4ZG	Resection of descending colon, percutaneous endoscopic approach, hand-assisted	Y	05 06 17 17 21 24	264 329-331 820-822 826-828 907-909 957-959
0DTN4ZG	Resection of sigmoid colon, percutaneous endoscopic approach, hand-assisted	Y	06 11 17 17 21 24	329-331 673-675 820-822 826-828 907-909 957-959
0DXU0ZV	Transfer omentum to thoracic region, open approach	Y	04 21 24	166-168 907-909 957-959
0DXU0ZW	Transfer omentum to abdominal region, open approach	Y	06 21 24	353-355 907-909 957-959
0DXU0ZX	Transfer omentum to pelvic region, open approach	Y	06	350-352
0DXU0ZY	Transfer omentum to inguinal region, open approach	Y	06	350-352
0DXU4ZV	Transfer omentum to thoracic region, percutaneous endoscopic approach	Y	04 21 24	166-168 907-909 957-959
0DXU4ZW	Transfer omentum to abdominal region, percutaneous endoscopic approach	Y	06 21 24	353-355 907-909 957-959
0DXU4ZX	Transfer omentum to pelvic region, percutaneous endoscopic approach	Y	06	350-352
0DXU4ZY	Transfer omentum to inguinal region, percutaneous endoscopic approach	Y	06	350-352
0FB04ZG	Excision of liver, percutaneous endoscopic approach, hand-assisted	Y	07 21	405-407 907-909

			24	957-959
0FB14ZG	Excision of right lobe liver, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0FB24ZG	Excision of left lobe liver, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0FBG4ZG	Excision of pancreas, percutaneous endoscopic approach, hand-assisted	Y	07 10 21 24	405-407 628-630 907-909 957-959
0FT04ZG	Resection of liver, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0FT14ZG	Resection of right lobe liver, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0FT24ZG	Resection of left lobe liver, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0FT44ZG	Resection of gallbladder, percutaneous endoscopic approach, hand-assisted	Y	06 07 07 17 17 21 24	356-358 411-413 417-419 820-822 826-828 907-909 957-959
0FTG4ZG	Resection of pancreas, percutaneous endoscopic approach, hand-assisted	Y	07 21 24	405-407 907-909 957-959
0TT04ZG	Resection of right kidney, percutaneous endoscopic approach, hand-assisted	Y	11 21 24	656-661 907-909 957-959
0TT14ZG	Resection of left kidney, percutaneous endoscopic approach, hand-assisted	Y	11 21 24	656-661 907-909 957-959
0TT24ZG	Resection of bilateral kidneys, percutaneous endoscopic approach, hand-assisted	Y	11 21 24	656-661 907-909 957-959
3E0L317*	Introduction of other thrombolytic into pleural cavity, percutaneous approach	N		
XW01329*	Introduction of talquetamab antineoplastic into subcutaneous tissue, percutaneous approach, new technology group 9	N		
XX2KXP9*	Monitoring of interstitial fluid volume, sub-epidermal moisture using electrical biocapacitance, external approach, new technology group 9	N		

*As the procedure codes are designated as non-O.R. procedures, there is no assigned MDC or MS-DRG. The ICD-10 MS-DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a complication or comorbidity (CC) or major complication or comorbidity (MCC), procedures or services performed, age, sex, and discharge status.

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The 41 procedure codes are also reflected in Table 6B- New Procedure Codes, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* We are soliciting public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2025, as well as any other options for the GROUPER logic.

We note that Change Request (CR) 13458, Transmittal 12384, titled ''April 2024 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 41.1'' was issued on November 30, 2023 (available on the CMS website at: *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2023-transmittals/r12384cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 41.1, effective with discharges on and after April 1, 2024, reflecting the new procedure codes. The updated software, along with the updated ICD–10 MS–DRG Version 41.1 Definitions Manual and the Definitions of Medicare Code Edits Version 41.1 manual is available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of the Medicare Modernization Act (Pub. L. 108–173) included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

However, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. With this new April 1 update, CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We are continuing to use several aspects of our existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes efforts to accommodate the requested implementation date for each request submitted. However, the Committee determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. As discussed earlier in this section of the preamble of this proposed rule, there were code proposals presented for an April 1, 2024 implementation at the September 12–13, 2023 Committee meetings. Following the receipt of public comments, the code proposals were approved and finalized, therefore, there were new codes implemented April 1, 2024.

Consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2023 and provided the updated code files in December 2023 and ICD–10–CM Official Guidelines for Coding and Reporting in January 2024. In the February 05, 2024 **Federal Register** (89 FR 7710), notice for the March 19–20, 2024 ICD–10 Coordination and Maintenance Committee Meeting was published that includes the tentative agenda and identifies which topics are related to a new technology add-on payment application. By February 1, 2024 we made available the updated Version 41.1 ICD–10 MS–DRG GROUPER software and related materials on the CMS web page at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

ICD–9–CM addendum and code title information is published on the CMS website at *https://www.cms.gov/medicare/coding-billing/icd-10-codes/updates-revisions-icd-9-cm-procedure-codes-addendum.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at *https://www.cms.gov/medicare/coding-billing/icd-10-codes.* CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at *https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm.*

Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

For FY 2024, there are currently 74,044 diagnosis codes and 78,638 procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this proposed rule (and available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*), there are 252 new diagnosis codes that have been finalized for FY 2025 at the time of the development of this proposed rule and 41 new procedure codes that were effective with discharges on and after April 1, 2024. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to provide the October updates in this manner in the IPPS proposed and final rules.

16. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2025

As discussed in section II.C.5. of the preamble of this proposed rule, for FY 2025, we are proposing to revise the title of MS–DRG 276 from ''Cardiac Defibrillator Implant with MCC'' to ''Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator''.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRG 276 is on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the following table. Therefore, we are proposing that if the applicable proposed MS–DRG changes are finalized, we would make conforming changes to the title of MS–DRG 276 as reflected in the table that follows. We are also proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

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MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC

05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
05	276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
05	277	Cardiac Defibrillator Implant without MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

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The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2025 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

D. Recalibration of the FY 2025 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2025, we propose to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2023 MedPAR data used in this proposed rule include discharges occurring on October 1, 2022, through September 30, 2023, based on bills received by CMS through December 31, 2023, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2023 MedPAR file used in calculating the relative weights includes data for approximately 6,887,902 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 2023 update of the FY 2023 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2025 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. In addition, the data exclude Rural Emergency Hospitals (REHs), including hospitals that subsequently became REHs after the period from which the data were taken. We note that the proposed FY 2025 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2023 MedPAR claims data, grouped through the ICD–10 version of

the proposed FY 2025 GROUPER (Version 42).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the Healthcare Cost Report Information System (HCRIS). In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this proposed rule, we used the December 2023 update of the FY 2022 HCRIS for calculating the FY 2025 cost-based relative weights. Consistent with our historical practice, for this FY 2025 proposed rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. Click on the link on the left side of the screen titled ''FY 2025 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the proposed FY 2025 relative weights based on 19 CCRs. The methodology we are proposing to use to calculate the FY 2025 MS–DRG cost-based relative weights based on claims data in the FY 2023 MedPAR file and data from the FY 2022 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2025 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2023 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.6 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a Present on Admission (POA) field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting

process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services that beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced.* Consistent with our policy for FY 2024, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2025, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2024 IPPS/LTCH PPS final rule, we are also proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2022 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this proposed rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2025 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to the following: MS–DRG 016 and MS–DRG 017, MS–DRG 095 and MS–DRG 096, MS–DRG 504 and MS–DRG 505, MS–DRG 797 and MS–DRG 798. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2025 relative weights and the changes in relative weights from FY 2024.

b. Relative Weight Calculation for MS–DRG 018

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies. We also finalized our proposal to modify our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs (85 FR 58599 through 58600). Specifically, we stated that clinical trial claims that group to new MS–DRG 018 would not be included when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. We stated that we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the FY 2021 final rule. In addition, we stated that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data.

We also finalized our proposal to calculate an adjustment to account for

the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations. We calculate this adjustor by dividing the average cost for cases that we identify as clinical trial cases by the average cost for cases that we identify as non-clinical trial cases, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. We stated that to the best of our knowledge, there were no claims in the historical data used in the calculation of this adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access use immunotherapy cases that group to MS–DRG 018, and indicated that we would provide instructions for identifying these claims in separate guidance. Following the issuance of the FY 2021 IPPS/LTCH PPS final rule, we issued guidance [15] stating that providers may enter a Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim to notify the MAC of expanded access use of CAR T-cell therapy. In this case, the MAC would add payer-only condition code ''ZB'' so that Pricer will apply the payment adjustment in calculating payment for the case. In cases when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the provider may enter a Billing Note NTE02 ''Diff Prod Clin Trial'' on the electronic claim 837I or a remark ''Diff Prod Clin Trial'' on a paper claim. In this case, the MAC would add payer-only condition code ''ZC'' so that the Pricer will not apply the payment adjustment in calculating payment for the case.

In the FY 2022 IPPS/LTCH PPS final rule, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 44806). We also finalized our proposal to continue to use the proxy of standardized drug charges of less than $373,000 (86 FR 44965) to identify clinical trial claims. We also finalized use of this same proxy for the FY 2023 IPPS/LTCH PPS final rule (87 FR 48894).

Following the issuance of the FY 2023 IPPS/LTCH PPS final rule, we issued guidance [16] stating where there is expanded access use of immunotherapy, the provider may submit condition code ''90'' on the claim so that Pricer will apply the payment adjustment in calculating payment for the case. We stated that MACs would no longer append Condition Code 'ZB' to inpatient claims reporting Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim, effective for claims for discharges that occur on or after October 1, 2022.

In the FY 2024 IPPS/LTCH PPS final rule, we explained that the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. We stated that for the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB, and for the FY 2023 MedPAR data and subsequent years, this field will identify whether or not the claim includes condition code 90. We further noted that the MedPAR files now also include a variable that indicates whether the claim includes the payer-only condition code ''ZC'', which identifies a case involving the clinical trial of a different product where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner.

Accordingly, and as discussed further in the FY 2024 IPPS/LTCH PPS final rule, we finalized two modifications to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 (88 FR 58791). First, we finalized to exclude claims with the presence of condition code ''90'' (or, for FY 2024 ratesetting, which was based on the FY 2022 MedPAR data, the presence of condition code ''ZB'') and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we finalized to no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018. Accordingly, we finalized that in calculating the relative weight for MS–DRG 018 for FY 2024, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (2) contain condition code ''ZB'' (or, for subsequent fiscal years, condition code ''90'') would be excluded from the calculation of the average cost for MS–DRG 018. Consistent with this, we also finalized modifications to our calculation of the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs. We refer readers to the FY 2024 IPPS/LTCH PPS final rule for further discussion of these modifications (88 FR 58791).

In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to continue to use our methodology as modified in the FY 2024 IPPS/LTCH PPS final rule for identifying clinical trial claims and expanded access use claims in MS–DRG 018. First, we exclude claims with the presence of condition code ''90'' and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018. Accordingly, we are proposing that in calculating the relative weight for MS–DRG 018 for FY 2025, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (2) contain condition code ''90'' would be excluded from the calculation of the average cost for MS–DRG 018.

We are also proposing to continue to use the methodology as modified in the FY 2024 IPPS/LTCH PPS final rule to calculate the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

[15] *https://www.cms.gov/files/document/r10571cp.pdf.*

[16] *https://www.cms.gov/files/document/r11727cp.pdf.*

- Calculate the average cost for cases assigned to MS–DRG 018 that either (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'' or (b) contain condition code ''90''.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as applicable clinical trial or expanded access use cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Under our proposal to continue to apply this methodology, based on the December 2023 update of the FY 2023 MedPAR file used for this proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($116,831) were 34 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($342,684). Accordingly, as we did for FY 2024, we are proposing to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 0.34 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by 0.34. As we did for FY 2024, we are applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

d. Cap for Relative Weight Reductions

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. We also finalized a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the permanent 10-percent cap does not result in an increase or decrease of estimated aggregate payments. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion of this policy. In the Addendum to this IPPS/LTCH PPS proposed rule, we present the proposed budget neutrality adjustment for reclassification and recalibration of the FY 2025 MS–DRG relative weights with application of this cap. We are also making available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for FY 2025. For a further discussion of the proposed budget neutrality adjustment for FY 2025, we refer readers to the Addendum of this proposed rule.

3. Development of Proposed National Average Cost-To-Charge Ratios (CCRs)

We developed the proposed national average CCRs as follows:

Using the FY 2022 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight. The proposed FY 2025 cost-based relative weights were then normalized by an adjustment factor of 1.92287 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act. We then applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year; specifically for those MS–DRGs for which the relative weight otherwise would have declined by more than 10 percent from the FY 2024 relative weight, we set the proposed FY 2025 relative weight equal to 90 percent of the FY 2024 relative weight. The proposed relative weights for FY 2025 as set forth in Table 5 associated with this proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this cap.

The proposed 19 national average CCRs for FY 2025 are as follows:

Proposed National Average CCRs	
Group	**CCR**
Routine Days	0.417
Intensive Days	0.364
Drugs	0.182
Supplies & Equipment	0.302
Implantable Devices	0.270
Inhalation Therapy	0.163
Therapy Services	0.269
Anesthesia	0.075
Labor & Delivery	0.385
Operating Room	0.162
Cardiology	0.089
Cardiac Catheterization	0.106
Laboratory	0.103
Radiology	0.129
MRIs	0.068
CT Scans	0.033
Emergency Room	0.155
Blood and Blood Products	0.253
Other Services	0.341

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2025. Using data from the FY 2023 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. For FY 2025, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2024 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2024 to FY 2025. The crosswalk table is as follows.

Low-Volume MS-DRGs		
Low-Volume MS-DRG	**MS-DRG Title**	**Crosswalk to MS-DRG**
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
797	Vaginal delivery with sterilization and/or D&C with CC	Final FY 2024 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

E. Add-On Payments for New Services and Technologies for FY 2025

1. Background

Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d).

We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-on Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar''

to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2025 are presented in a data file that is available, along with the other data files associated with the FY 2024 IPPS/LTCH PPS final rule and correction notification, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2026 are presented in a data file that is available on the CMS website, along with the other data files associated with the FY 2025 proposed rule, by clicking on the FY 2025 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient. The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a

demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what services and technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. To receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, a medical device designated under FDA's Breakthrough Devices Program that has received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d). We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy.

We note that, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive FDA marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The

payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

We note that, consistent with the prospective nature of the IPPS, we finalize the new technology add on payment amount for technologies approved or conditionally approved for new technology add-on payments in the final rule for each fiscal year and do not make mid-year changes to new technology add-on payment amounts. Updated cost information may be submitted and included in rulemaking to be considered for the following fiscal year.

Section 503(d)(2) of the MMA (Pub. L. 108–173) provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of the MMA, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment (85 FR 58742).

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we finalized that, beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant

has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958). We also finalized that, beginning with FY 2025 applications, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA approval or clearance by May 1 (rather than July 1) of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products), as reflected at §§ 412.87(f)(2) and (f)(3), as amended and redesignated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958, 88 FR 59331).

e. New Technology Liaisons

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS has established a team of new technology liaisons that can serve as an initial resource for interested parties. This team is available to assist with all of the following:

- Help to point interested parties to or provide information and resources where possible regarding process, requirements, and timelines.
- Coordinate and facilitate opportunities for interested parties to engage with various CMS components.
- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We receive many questions from parties interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech,* we know that there may be additional questions about the application process. Interested parties with further questions regarding Medicare's coverage, coding, and payment processes, and how they can navigate these processes, whether for new technology add-on payments or otherwise, should review the updated resource guide available at: *https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties.* Parties that would like to further discuss questions or concerns with CMS should contact the new technology liaison team at *MedicareInnovation@cms.hhs.gov.*

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2026 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. CMS will review the application based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2026, once the application deadline has closed, CMS will post on its website a list of the applications submitted, along with a brief description of each technology as provided by the applicant.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized our proposal to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We also finalized that with the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly, and that we will not post applications that are withdrawn prior to publication of the proposed rule. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) for further information regarding this policy.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347 and has an expiration date of December 31, 2026.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of the MMA, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2025 prior to publication of the FY 2025 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on September 28, 2023 (88 FR 66850) and held a virtual town hall meeting on

December 13, 2023. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2025 new medical service and technology add-on payment applications before the publication of the FY 2025 IPPS/LTCH IPPS proposed rule.

Approximately 130 individuals registered to attend the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.* We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 18, 2023 deadline, in our evaluation of the new technology add-on payment applications for FY 2025 in the development of the FY 2025 IPPS/LTCH PPS proposed rule. In response to the published notice and the December 13, 2023 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2025 new technology add-on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (88 FR 66850 through 66853), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2025. Therefore, we are not summarizing any written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.E.5. of the preamble of the proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10,* including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. Proposed FY 2025 Status of Technologies Receiving New Technology Add-On Payments for FY 2024

In this section of the proposed rule, we discuss the proposed FY 2025 status of 31 technologies approved for FY 2024 new technology add-on payments, as set forth in the tables that follow. Specifically, we present our proposals to continue the new technology add-on payments for FY 2025 for those technologies that were approved for the new technology add-on payment for FY 2024, and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2025. We also present our proposals to discontinue new technology add-on payments for FY 2025 for those technologies that were approved for the new technology add-on payment for FY 2024, and which would no longer be considered ''new'' for purposes of new technology add-on payments for FY 2025.

Additionally, we note that we conditionally approved DefenCath™ (taurolidine/heparin) for FY 2024 new technology add-on payments under the alternative pathway for certain antimicrobial products (88 FR 58942 through 58944), subject to the technology receiving FDA marketing authorization by July 1, 2024. DefenCath™ (taurolidine/heparin) received FDA marketing authorization on November 15, 2023, and was eligible to receive new technology add-on payments in FY 2024 beginning with discharges on or after January 1, 2024. As DefenCath™ (taurolidine/heparin) received FDA marketing authorization prior to July 1, 2024, and was approved for new technology add-on payments in FY 2024, we are proposing to continue making new technology add-on payments for taurolidine/heparin for FY 2025.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

Table II.E.—01 lists the technologies for which we are proposing to continue making new technology add-on payments for FY 2025 because they are still considered ''new'' for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We are inviting public comments on our proposals to continue new technology add-on payments for FY 2025 for the technologies listed in the following table.

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TABLE II.E.-01: PROPOSED CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2024 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2025 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER APRIL 1, 2025

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2025	Coding Used to Identify Cases Eligible for NTAP
1	*Thoraflex™ Hybrid Device*	*04/19/2022*	*10/1/2022*	*04/19/2025*	87 FR 48974 through 48975 88 FR 58800	$22,750.00	X2RX0N7 in combination with X2VW0N7
2	*ViviStim® Paired VNS System*	*04/29/2022*	*10/1/2022*	*04/29/2025*	87 FR 48975 through 48977 88 FR 58800	$23,400.00	X0HQ3R8
3	*GORE® TAG® Thoracic Branch Endoprosthesis*	*05/13/2022*	*10/1/2022*	*05/13/2025*	87 FR 48966 through 48969 88 FR 58800	$27,807.00	02VW3DZ in combination with 02VX3EZ
4	*Cerament® G*	*05/17/2022*	*10/1/2022*	*05/17/2025*	87 FR 48961 through 48966 88 FR 58800	$4,918.55	XW0V0P7
5	*iFuse Bedrock Granite Implant System*	*05/26/2022*	*10/1/2022*	*05/26/2025*	87 FR 48969 through 48974 88 FR 58800	$9,828.00	XNH6058 or XNH6358 or XNH7058 or XNH7358 or XRGE058 or XRGE358 or XRGF058 or XRGF358
6	*CYTALUX® (pafolacianine) (ovarian indication)*	*04/15/2022*	*10/1/2023*	*04/15/2025*	88 FR 58804 through 58810	$2,762.50	8E0U0EN, 8E0U3EN, 8E0U4EN, 8E0U7EN, or 8E0U8EN
7	*CYTALUX® (pafolacianine) (lung indication)*	*06/05/2023*	*10/1/2023*	*06/05/2026*	88 FR 58810 through 58818	$2,762.50	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN
8	*EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)*	*05/19/2023*	*10/1/2023*	*05/19/2026*	88 FR 58818 through 58835	$6,504.07	XW013S9, XW033P9, or XW043P9
9	*Lunsumio™ (mosunetuzumab)*	*12/22/2022*	*10/1/2023*	*12/22/2025*	88 FR 58835 through 58845	$17,492.10	XW03358 or XW04358
10	*REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk)*	*01/23/2023*	*10/1/2023*	*01/23/2026*	88 FR 58848 through 58868	$6,789.25	XW0H7X8 or XW0DXN9
11	*SPEVIGO® (spesolimab)*	*09/01/2022*	*10/1/2023*	*09/01/2025*	88 FR 58879 through 58885	$33,236.45	XW03308
12	*TECVAYLI™ (teclistamab-cqyv)*	*11/09/2022*	*10/1/2023*	*11/09/2025*	88 FR 58885 through 58891	$8,940.54	XW01348
13	*TERLIVAZ® (terlipressin)*	*10/14/2022*	*10/1/2023*	*10/14/2025*	88 FR 58891 through 58906	$16,672.50	XW03367 or XW04367
14	*Aveir™ AR Leadless Pacemaker*	*06/29/2023*	*10/1/2023*	*06/29/2026*	88 FR 58919 through 58923	$10,725.00	X2H63V9
15	*Aveir™ Dual-Chamber Leadless Pacemaker*	*06/29/2023*	*10/1/2023*	*06/29/2026*	88 FR 58923 through 58925	$15,600.00	X2H63V9 in combination with X2HK3V9
16	*Ceribell Status Epilepticus Monitor*	*05/23/2023*	*10/1/2023*	*05/23/2026*	88 FR 58927 through 58930	$913.90	XX20X89
17	*DETOUR System*	*06/07/2023*	*10/1/2023*	*06/07/2026*	88 FR 58930 through 58932	$16,250.00	X2KH3D9, X2KH3E9, X2KJ3D9, or X2KJ3E9
18	*DefenCath™ (taurolidine/heparin)*	*11/15/2023*	*1/1/2024*	*11/15/2026*	88 FR 58942 through 58944	$17,111.25	XY0YX28
19	*EchoGo Heart Failure 1.0*	*11/23/2022*	*10/1/2023*	*11/23/2025*	88 FR 58932 through 58935	$1,023.75	XXE2X19
20	*Phagenyx® System*	*04/12/2023*	*10/1/2023*	*04/12/2026*	88 FR 58935 through 58937	$3,250.00	XWHD7Q7

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2025	Coding Used to Identify Cases Eligible for NTAP
21	*REZZAYO™ (rezafungin for injection)*	*03/22/2023*	*10/1/2023*	*03/22/2026*	88 FR 58944 through 58946	$4,387.50	XW033R9 or XW043R9
22	*SAINT Neuromodulation System*	*09/01/2022*	*10/1/2023*	*09/01/2025*	88 FR 58937 through 58939	$12,675.00	X0Z0X18
23	*TOPS™ System*	*06/15/2023*	*10/1/2023*	*06/15/2026*	88 FR 58940 through 58942	$11,375.00	XRHB018 in combination with M48.062
24	*XACDURO® (sulbactam/durlobactam)*	*05/23/2023*	*10/1/2023*	*05/23/2026*	88 FR 58946 through 58948	$13,680.00	XW033K9 or XW043K9 in combination with one of the following: Y95 and J15.61; OR J95.851 and B96.83

Table II.E.-02 lists the technologies for which we are proposing to discontinue making new technology add-on payments for FY 2025 because they are no longer ''new'' for purposes of new technology add-on payments. This table

also presents the newness start date, for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date. We are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2025 for the technologies listed in Table II.E.-02.

new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We refer readers to the cited final rules in the following table

TABLE II.E.-02: PROPOSED DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2024 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2025 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2025

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations
1	*Intercept® Fibrinogen Complex (PRCFC)*	*05/05/2021*	*10/1/2021*	*5/05/2024*	86 FR 45149 through 45150 86 FR 67875 87 FR 48913 88 FR 58800
2	*Rybrevant® (amivantamab)*	*05/21/2021*	*10/1/2021*	*05/21/2024*	86 FR 44988 through 44996 87 FR 48913 88 FR 58800
3	*StrataGraft®*	*06/15/2021*	*10/1/2021*	*06/15/2024*	86 FR 45079 through 45090 87 FR 48913 88 FR 58800
4	*aprevo® Intervertebral Body Fusion Device (TLIF indication)*	*6/30/2021 (TLIF)*	*10/1/2021*	*6/30/2024 (TLIF)*	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913 88 FR 58800
5	*Hemolung Respiratory Assist System (RAS) (non-COVID-19 related use)*	*11/15/2021 (other)*	*10/1/2022*	*11/15/2024 (other)*	87 FR 48937 through 48948 88 FR 58800
6	*Livtencity™ (maribavir)*	*12/2/2021*	*10/1/2022*	*12/2/2024*	87 FR 48948 through 48954 88 FR 58800
7	*Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System*	*10/04/2021*	*10/1/2023*	*10/04/2024*	88 FR 58925 through 58927

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6. Proposed FY 2025 Applications for New Technology Add-On Payments (Traditional Pathway)

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our policy to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we are continuing to summarize each application in this proposed rule. However, while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2025 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2025 new technology add-on payment applications.

We received 16 applications for new technology add-on payments for FY 2025 under the new technology add-on payment traditional pathway. As discussed previously, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958). Of the 16 applications received under the traditional pathway, one applicant was not eligible for consideration for new technology add-on payment because it did not meet these requirements, and three applicants withdrew their application prior to the issuance of this proposed rule. In accordance with the regulations under § 412.87(f), applicants for FY 2025 new technology add-on payments must have received FDA approval or clearance by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We are addressing the remaining 12 applications. We note that the manufacturer for Casgevy™ (exagamglogene autotemcel) submitted a single application, but for two separate indications, each of which is discussed separately in this section.

a. CASGEVY™ (exagamglogene autotemcel) First Indication: Sickle Cell Disease (SCD)

Vertex Pharmaceuticals, Inc. submitted an application for new technology add-on payments for Casgevy™ for FY 2025 for use in sickle cell disease. According to the applicant, Casgevy™ is a one-time, clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9) modified autologous cluster of differentiation (CD)34+ hematopoietic stem & progenitor cell (HSPC) cellular therapy approved for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOC). Per the applicant, using a CRISPR/Cas9 gene editing technique, the patient's CD34+ HSPCs are edited ex vivo via Cas9, a nuclease enzyme that uses a highly specific guide ribonucleic acid (gRNA), at the critical transcription factor binding site GATA1 in the erythroid specific enhancer region of the B-cell lymphoma/leukemia 11A (BCL11A) gene. According to the applicant, as a result of the editing, GATA1 binding is irreversibly disrupted, and BCL11A expression is reduced, resulting in an increased production of fetal hemoglobin (HbF), and recapitulating a naturally occurring, clinically benign condition called hereditary persistence of fetal hemoglobin (HPFH) that reduces or eliminates SCD symptoms. As stated by the applicant, Casgevy™ infusion induces increased HbF production in SCD patients to ≥20 percent, which is known to be associated with fewer SCD complications via addressing the underlying cause of SCD by preventing RBC sickling. We note that the applicant is also seeking new technology add-on payments for Casgevy™ for FY 2025 for use in treating transfusion-dependent beta thalassemia (TDT), as discussed separately later in this section.

Please refer to the online application posting for Casgevy™, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310171VPTU,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, Casgevy™ was granted Biologics License Application (BLA) approval from FDA on December 8, 2023, for treatment of SCD in patients 12 years of age or older with recurrent VOCs. According to the applicant, Casgevy™ became commercially available immediately after FDA approval. Casgevy™ is available in 20 mL vials containing 4 to 13×10^6 CD34+ cells/mL frozen in 1.5 to 20 mL of solution. The minimum dose is 3×10^6 CD34+ cells per kg of body weight, which may be contained within multiple vials.

Effective April 1, 2023, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of Casgevy™: XW133J8 (Transfusion of exagamglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8) and XW143J8 (Transfusion of exagamglogene autotemcel into central vein, percutaneous approach, new technology group 8). The applicant provided a list of ICD–10–CM diagnosis codes that may be used to identify this indication for Casgevy™. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. We believe the relevant ICD–10–CM codes to identify the indication of SCD would be: D57.1 (Sickle-cell disease without crisis), D57.20 (Sickle-cell/Hb-C disease without crisis), D57.40 (Sickle-cell thalassemia without crisis), D57.42 (Sickle-cell thalassemia beta zero without crisis), D57.44 (Sickle-cell thalassemia beta plus without crisis), or D57.80 (Other sickle-cell disorders without crisis). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of SCD for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Casgevy™ is not substantially similar to other currently available technologies, because Casgevy™ is the

first approved therapy to use CRISPR gene editing technology and no other approved technology uses the same or a similar mechanism of action; and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Casgevy™ for the applicant's complete statements in support of its assertion that Casgevy™ is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Casgevy™ is the first technology to use the CRISPR/Cas9 gene editing mechanism of action. No other approved technologies use this mechanism of action, and CRISPR technology has never previously been used in humans outside of clinical trials. Casgevy™ is a one-time treatment that uses ex vivo non-viral CRISPR/Cas9 to precisely edit the erythroid-specific enhancer region of BCL11A in CD34+ HSPCs. The technology consists of the Cas9 nuclease and single guide RNA (sgRNA), which together form a ribonucleoprotein (RNP) complex. The Cas9/sgRNA complex binds DNA at a precise location, and Cas9 cuts the DNA strand, generating a DNA double-stranded break. Naturally occurring DNA repair systems are activated to resolve the double-strand break. These changes in the target DNA sequence suppress the BCL11A gene and reactivate production of HbF. While other therapeutic approaches such as Hydroxyurea impact production of HbF, no other approved technology has been able to reactivate production of endogenous HbF to levels known to eliminate disease complications (for example, VOCs), consistent with individuals with a clinically benign condition called HPFH who experience no or minimal disease complications from SCD when they co-inherit both HPFH and SCD.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	In the FY 2024 IPPS Final Rule, CMS finalized assignment of the ICD-10-PCS codes (XW133J8 and XW143J8) describing the transfusion of Casgevy™ to MS-DRGs 016 and 017. MS-DRGs 016 and 017 are also currently used for autologous stem-cell transplants but not allogeneic stem cell transplants currently used in the treatment of SCD. Allogeneic stem cell transplants are reimbursed on a reasonable cost basis by operation of section 1886(d)(5)(M) of the Social Security Act.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	Casgevy™ is the first therapy to use the CRISPR/Cas9 gene editing mechanism of action. There are currently several approved therapies that are used to treat patients living with SCD. However, no other approved single product would act as a stand-alone one-time treatment intended permanently to address the root cause of SCD.

We note that Casgevy™ may have the same or similar mechanism of action to Lyfgenia™, for which we also received an application for new technology add-on payments for FY 2025. Casgevy™ and Lyfgenia™ are both gene therapies using modified autologous CD34+ hematopoietic stem and progenitor cell (HSPC) therapies administered via stem cell transplantation for the treatment of SCD. Lyfgenia™ was approved by FDA for this indication on December 8, 2023. We note that both technologies are autologous, ex-vivo modified hematopoietic stem-cell biological products. For these technologies, patients are required to undergo CD34+ HSPC mobilization followed by apheresis to extract CD34+ HSPCs for manufacturing and then myeloablative conditioning using busulfan to deplete the patient's bone marrow in preparation for the technologies' modified stem cells to engraft to the bone marrow. Once engraftment occurs for both technologies, the patient's cells start to produce a different form of hemoglobin in order to reduce the sickling hemoglobin. Further, both technologies appear to map to the same MS–DRGs, MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and 017 (Autologous Bone Marrow Transplant without CC/MCC), and to treat the same or similar disease (sickle cell disease) in the same or similar patient population (patients 12 years of age and older who have a history of vaso-occlusive events). Accordingly, as it appears that Casgevy™ and Lyfgenia™ may use the same or similar mechanism of action to achieve a therapeutic outcome (that is, to reduce the amount of sickling hemoglobin to reduce and prevent VOEs associated with SCD), would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We note that if we determine that this technology is substantially similar to Lyfgenia™, we believe the newness period would begin on December 8, 2023, the date both Casgevy™ and Lyfgenia™ received FDA approval for SCD. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether Casgevy™ and Lyfgenia™ are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comments on whether Casgevy™ meets the newness criterion, including whether Casgevy™ is substantially similar to Lyfgenia™ and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, the applicant searched the FY 2022 MedPAR and provided multiple analyses to demonstrate that Casgevy™ meets the cost criterion. The applicant included two cohorts in the analyses to identify potential cases representing patients who may be eligible for Casgevy™: the first cohort included all cases in MS–DRG 014 (Allogeneic Bone Marrow Transplant) to account for the low volume of SCD or transfusion-dependent beta thalassemia (TDT) cases,

and the second cohort included cases in MS–DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD–10–CM diagnosis code of SCD or TDT. The applicant explained that the cost analyses for SCD and TDT were combined because the volume of cases with a sickle cell disease or beta thalassemia diagnosis code was very low, and because it believed both indications would be approved in time for new technology add-on payment. In addition, the applicant noted that when searching for cases in DRG 014 with SCD or beta thalassemia diagnosis codes, there were no beta thalassemia cases. The applicant noted that cases included in the analysis may not be a completely accurate representation of cases that will be eligible for Casgevy™ but that the analyses were provided in recognition of the low volume of cases.

The applicant performed two analyses for each cohort: one with all prior drug charges maintained, representing a scenario in which there is no change to patient drug regimen with the use of Casgevy™; and the other with all prior drug charges removed, representing a scenario in which no ancillary drugs are used in the treatment of Casgevy™ patients. Per the applicant, this was done because some patients receiving Casgevy™ could receive fewer ancillary drugs during the inpatient stay, but it was difficult to know with certainty whether this would be the case or to identify the exact differences in drug regimens between patients receiving Casgevy™ and those receiving allogeneic bone marrow transplants. The applicant noted the analyses with drug charges removed were likely an over-estimation of the ancillary drug charges that would be removed in cases involving the use of Casgevy™, but these were provided as sensitivity analyses.

According to the applicant, eligible cases for Casgevy™ will be mapped to either Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) or Pre-MDC MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC), depending on whether complications or comorbidities (CCs) or major complications or comorbidities (MCCs) are present. For each analysis, the applicant used the FY 2025 new technology add-on payment threshold for Pre-MDC MS–DRG 016 for all identified cases, because it was typically higher than the threshold for Pre-MDC MS–DRG 017. Each analysis followed the order of operations described in the table later in this section.

For the first cohort, the applicant included all cases associated with MS–DRG 014 (Allogeneic Bone Marrow Transplant). The applicant used the inclusion/exclusion criteria described in the following table and identified 996 claims mapping to MS–DRG 014. With all prior drug charges maintained (Scenario 1), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,325,062, which exceeded the average case-weighted threshold amount of $182,491. With all prior drug charges removed (Scenario 2), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,181,526, which exceeded the average case-weighted threshold amount of $182,491.

For the second cohort, the applicant searched for cases within MS–DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD–10–CM diagnosis codes representing SCD or TDT. The applicant used the inclusion/exclusion criteria described in the following table and identified 11 claims mapping to MS–DRG 014 (Allogeneic Bone Marrow Transplant). With all prior drug charges maintained (Scenario 3), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,125,212, which exceeded the average case-weighted threshold amount of $182,491. With all prior drug charges removed (Scenario 4), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,086,551, which exceeded the average case-weighted threshold amount of $182,491.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant maintained that Casgevy™ meets the cost criterion.

CASGEVY™ COST ANALYSIS[17]	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for Casgevy™.
List of MS-DRGs	014 (Allogeneic Bone Marrow Transplant with CC/MCC)
Inclusion/ exclusion criteria	Cohort 1: The applicant included all cases assigned to MS-DRG 014 (Allogeneic Bone Marrow Transplant). Cohort 2: The applicant searched for cases within MS-DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD-10-CM diagnosis codes representing SCD or TDT using the codes listed in the online posting for Casgevy™.
Charges removed for prior technology	Scenarios 1 and 3 (the first scenario of each cohort): The applicant removed 100% of charges associated with allogeneic bone marrow transplants, as treatment with Casgevy™ would eliminate the need for an allo-HSCT. The applicant did not remove any indirect charges related to ancillary drugs. Scenarios 2 and 4 (the second scenario of each cohort): The applicant removed 100% of charges associated with allogeneic bone marrow transplants, as treatment with Casgevy™ would eliminate the need for an allo-HSCT. The applicant removed all indirect charges related to ancillary drugs.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.9% to the standardized charges, based on the two-year inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether Casgevy™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Casgevy™ represents a substantial clinical improvement over existing technologies because it is anticipated to expand patient eligibility for potentially curative SCD therapies, have improved clinical outcomes relative to available therapies, and avoid certain serious risks or side effects associated with existing potentially curative treatment options for SCD. The applicant provided one study to support these claims, as well as eight background articles about clinical outcomes and safety risks of other SCD treatments.[18] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Casgevy™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[17] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachments included in the online posting for the technology.

[18] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.	
Applicant statements in support	**Supporting evidence provided by the applicant**
Casgevy™ is anticipated to expand patient eligibility for potentially curative therapies for SCD due to the lack of necessity for HLA-matching as an autologous therapy.	CASGEVY (exagamglogene autotemcel) [package insert]. Boston, MA: Vertex Pharmaceuticals, Inc.; 2023 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.	
Applicant statements in support	**Supporting evidence provided by the applicant**
Casgevy™ is the first gene therapy specifically approved for the treatment of SCD in patients 12 years and older with recurrent VOCs.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Casgevy™ is anticipated to have significantly improved clinical outcomes relative to available therapies as shown by elimination of severe VOCs in SCD patients 12 years and older with recurrent VOCs.	Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023. Frangoul H, et al. Presented at the 65th Annual American Society of Hematology. 11 Dec 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Casgevy™ is expected to avoid certain serious risks or side effects associated with approved viral-based gene therapies for SCD.	CASGEVY (exagamglogene autotemcel) [package insert]. Boston, MA: Vertex Pharmaceuticals, Inc.; 2023. % Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Casgevy™ is expected to avoid certain serious risks or side effects associated with existing potentially. curative treatment options for SCD.	Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

After review of the information provided by the applicant, we have the following concerns regarding whether Casgevy™ meets the substantial clinical improvement criterion. We note that the only assessment of the technology submitted was from conference presentations that provide data on the ongoing CLIMB–121 trial, a phase 1/2/3 single-arm trial assessing a single dose of Casgevy™ in patients 12 to 35 years old with SCD and a history of 2 or more severe VOCs per year over 2 years. The most recent data presented at ASH in December 2023,[19] which appears to supersede the earlier results from Locatelli et al. (2023),[20] indicates 44 participants received Casgevy™ for SCD, of which only 30 participants were evaluable for the primary and key secondary endpoints because they were followed for at least 16 months (up to 45.5 months) post Casgevy™ infusion. The applicant stated 96.7% of patients achieved the primary efficacy endpoint (free of severe VOCs for at least 12 consecutive months) and 100% of patients achieved the key secondary efficacy endpoint (free from in-patient hospitalization for severe VOCs for at least 12 consecutive months). Additionally, the applicant noted a safety profile consistent with myeloablative busulfan and autologous HSCT and that there were no malignancies nor serious adverse events related to Casgevy™. However, we note that the provided evidence did not include peer-reviewed literature that directly assessed the use of Casgevy™ for SCD. We also question whether the small study population may limit the generalizability of these study outcomes to a Medicare population. In addition, from the evidence submitted, we were also unable to determine where the study took place (that is, within the U.S. or in locations outside the U.S), which may also limit generalizability to the Medicare population. Additionally, we question if the short follow-up duration is sufficient to assess improvements in long-term clinical outcomes.

Furthermore, the applicant asserted that Casgevy™ significantly improves clinical outcomes relative to services or technologies previously available. Regarding the claim that Casgevy™ is the first gene therapy specifically approved for the treatment of SCD in patients 12 years and older with

[19] Frangoul H, et al. Presented at the 65th Annual American Society of Hematology. 11 Dec 2023.

[20] Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023.

recurrent VOCs, the applicant claims it was first to submit and have their BLA accepted for a genetic therapy for treatment of SCD. The applicant states the PDUFA date for Casgevy™ of December 8, 2023, and the PDUFA data for another gene therapy for SCD is December 20, 2023, and that Casgevy and another product were both approved on December 8, 2023, as the first gene therapies for SCD. However, while this claim was made in support of the assertion that Casgevy™ significantly improves clinical outcomes, we note that the information submitted regarding PDUFA dates and FDA approvals does not appear to provide data regarding a significantly improved clinical outcome under § 412.87(b)(1)(ii)(C).

With regards to the claim that Casgevy™ is expected to avoid certain serious risks or side effects associated with approved viral-based gene therapies for SCD, the applicant cites the potential risk of insertional oncogenesis after treatment with Lyfgenia™ per the package insert for this other gene therapy for SCD. We note that because clinical trials are conducted under widely varying conditions, we question whether adverse reaction rates observed in the clinical trials of one drug can be directly compared to rates in the clinical trials of another drug. We also question if the follow-up duration for patients treated with Casgevy™ is sufficient to assess improvement in the rate of malignancy.

With regard to the claim that Casgevy™ is expected to avoid certain serious risks or side effects associated with existing potentially curative treatment options for SCD, the applicant states that there are significant risks associated with allo-HSCT, including graft failure (up to 9 percent frequency), acute and chronic graft-versus-host disease (GVHD) (with chronic GVHD up to 18 percent frequency), severe infection, hematologic malignancy, bleeding events, and death. In contrast, the applicant claims Casgevy™ does not require an allogeneic donor as each patient is their own donor and therefore does not have risks of acute and chronic GVHD or immunologic risks of secondary graft failure/rejection, in addition to not requiring post-transplant immunosuppressive therapies. However, we would be interested in additional evidence regarding the frequency and clinical relevance of side effects such as severe infection, hematologic malignancy, bleeding events, and death for both therapies.

We are inviting public comments on whether Casgevy™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Casgevy™.

b. Casgevy™ (exagamglogene autotemcel) Second Indication: Transfusion-Dependent β-Thalassemia (TDT)

Vertex Pharmaceuticals, Inc. submitted an application for new technology add-on payments for Casgevy™ for FY 2025 for TDT. According to the applicant, Casgevy™ is a one-time, clustered regularly interspaced short palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9) modified autologous cluster of differentiation (CD)34+ hematopoietic stem & progenitor cell (HSPC) cellular therapy indicated for the treatment of transfusion-dependent β-thalassemia (TDT) in patients 12 years of age or older. Per the applicant, using a CRISPR/Cas9 gene editing technique, the patient's CD34+ HSPCs are edited ex vivo via Cas9, a nuclease enzyme that uses a highly specific guide ribonucleic acid (gRNA), at the critical transcription factor binding site GATA1 in the erythroid specific enhancer region of the B-cell lymphoma/leukemia 11A (BCL11A) gene. According to the applicant, as a result of the editing, GATA1 binding is irreversibly disrupted, and BCL11A expression is reduced, resulting in an increased production of fetal hemoglobin (HbF). As stated by the applicant, this increase in HbF recapitulates a naturally occurring, clinically benign condition called hereditary persistence of fetal hemoglobin (HPFH). The applicant states that as a result, Casgevy™ infusion induces increased HbF production in TDT patients so that circulating red blood cells (RBC) exhibit nearly 100 percent HbF, eliminating the need for RBC transfusions. As previously discussed earlier in this section, the applicant is also seeking new technology add-on payments for Casgevy™ for FY 2025 for use in treating SCD.

Please refer to the online application posting for Casgevy™, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310171VPTU,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, Casgevy™ was granted Biologics License Application (BLA) approval from FDA on January 16, 2024, for the treatment of TDT in patients 12 years of age and older. The applicant also explained that the minimum dosage of Casgevy™ is $3x10^6$ CD34 + cells per kg of patient's weight. A single dose of Casgevy™ is supplied in one or more vials, with each vial containing 4 to $13x10^6$ cells/mL suspended in 1.5 to 20 mL of cryo-preservative medium.

Effective April 1, 2023, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of Casgevy™: XW133J8 (Transfusion of exagamglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8) and XW143J8 (Transfusion of exagamglogene autotemcel into central vein, percutaneous approach, new technology group 8). The applicant provided a list of diagnosis codes that may be used to currently identify this indication for Casgevy™ under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. We believe the relevant ICD–10–CM codes to identify the indication of TDT would be: D56.1 (Beta thalassemia), D56.2 (Delta-beta thalassemia), or D56.5 (Hemoglobin E-beta thalassemia). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of TDT for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Casgevy™ is not substantially similar to other currently available technologies because Casgevy™ is the first approved therapy to use CRISPR gene editing as its mechanism of action, and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Casgevy™ for the applicant's complete statements in support of its assertion that Casgevy™ is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Casgevy™ is the first technology to use the CRISPR/Cas9 gene editing mechanism of action. No other approved technologies use this mechanism of action, and CRISPR technology has never previously been used in humans outside of clinical trials. Casgevy™ is a one-time treatment that uses ex vivo non-viral CRISPR/Cas9 to precisely edit the erythroid-specific enhancer region of BCL11A in CD34+ HSPCs. The technology consists of the Cas9 nuclease and single guide RNA (sgRNA), which together form a ribonucleoprotein (RNP) complex. The Cas9/sgRNA complex binds DNA at a precise location, and Cas9 cuts the DNA strand, generating a DNA double-stranded break. Naturally occurring DNA repair systems are activated to resolve the double-strand break. These changes in the target DNA sequence suppress the BCL11A gene and reactivate production of HbF. While other therapeutic approaches such as Hydroxyurea impact production of HbF, no other approved technology has been able to reactivate production of endogenous HbF to levels known to eliminate disease complications (for example, transfusion dependence), consistent with individuals with a clinically benign condition called HPFH who experience no or minimal disease complications from TDT when they co-inherit both HPFH and TDT. There is a currently approved viral-based gene therapy for treatment of adult and pediatric patients with ß-thalassemia who require regular RBC transfusions; however, this gene therapy, Zynteglo™ (betibeglogene autotemcel), utilizes a different mechanism of action, using a different technology called gene transfer to use a modified, inert lentivirus to add working exogenous copies of the beta-globin gene to increase functional hemoglobin A.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	In the FY 2024 IPPS final rule, CMS finalized assignment of the ICD-10-PCS codes (XW133J8 and XW143J8) describing the transfusion of exa-cel to MS-DRGs 016 and 017. MS-DRGs 016 and 017 are also currently used for autologous stem-cell transplants—but not allogeneic stem cell transplants currently used in the treatment of TDT. Allogeneic stem cell transplants are reimbursed on a reasonable cost basis by operation of section 1886(d)(5)(M) of the Act.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	Casgevy™ is the first therapy to use the CRISPR/Cas9 gene editing mechanism of action. No other approved single product would act as a stand-alone one-time treatment intended permanently to address the root cause of both SCD and TDT.

We question whether Casgevy™ may be the same or similar to other gene therapies used to treat TDT, specifically Zynteglo™, which was approved for treatment of TDT on August 17, 2022. Casgevy™ and Zynteglo™ are both gene therapies using modified autologous CD34+ HSPC therapies administered via stem cell transplantation for the treatment of TDT. Both technologies are autologous, ex-vivo modified hematopoietic stem-cell biological products. For these technologies, patients are required to undergo CD34+ HSPC mobilization followed by apheresis to extract CD34+ HSPCs for manufacturing and then myeloablative conditioning using busulfan to deplete the patient's bone marrow in preparation for the technologies' modified stem cells to engraft to the bone marrow. Once engraftment occurs, the patient's cells start to produce a different form of hemoglobin to increase total hemoglobin and reduce the need for RBC transfusions. Therefore, it appears as if Casgevy™ and Zynteglo™ would use a similar mechanism of action to achieve a therapeutic outcome for the treatment of TDT. Further, both technologies appear to map to the same MS–DRGs, MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and 017 (Autologous Bone Marrow Transplant without CC/MCC), and to treat the same or similar disease (beta thalassemia) in the same or similar patient population (patients who require regular blood transfusions). Accordingly, we believe that these technologies may be substantially similar to each other. We note that if Casgevy™ is substantially similar to Zynteglo™ for the treatment of TDT, we believe the newness period for this technology would begin on August 17, 2022, with the Biologics License Application (BLA) approval date for Zynteglo™.

We are inviting public comments on whether Casgevy™ is substantially similar to existing technologies and whether Casgevy™ meets the newness criterion.

With respect to the cost criterion, the applicant searched the FY 2022 MedPAR and provided multiple analyses to demonstrate that Casgevy™ meets the cost criterion. The applicant included two cohorts in the analyses to identify potential cases representing patients who may be eligible for Casgevy™: the first cohort included all cases in MS–DRG 014 (Allogeneic Bone Marrow Transplant) to account for the low volume of sickle cell disease (SCD) or TDT cases, and the second cohort included cases in MS–DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD–10–CM diagnosis code of SCD or TDT. The applicant explained that the cost analyses for SCD and TDT were combined because the volume of cases with a sickle cell disease or beta thalassemia diagnosis code was very small, and because it believed both indications would be approved in time

for new technology add-on payment. In addition, the applicant noted that when searching for cases in DRG 014 with SCD or beta thalassemia diagnosis codes, there were no beta thalassemia cases. The applicant noted that cases included in the analysis may not be a completely accurate representation of cases that will be eligible for Casgevy™ but that the analyses were provided in recognition of the low volume of cases.

The applicant performed two analyses for each cohort: one with all prior drug charges maintained, representing a scenario in which there is no change to patient drug regimen with the use of Casgevy™; and the other with all prior drug charges removed, representing a scenario in which no ancillary drugs are used in the treatment of Casgevy™ patients. Per the applicant, this was done because some patients receiving Casgevy™ could receive fewer ancillary drugs during the inpatient stay, but it was difficult to know with certainty whether this would be the case or to identify the exact differences in drug regimens between patients receiving Casgevy™ and those receiving allogeneic bone marrow transplants. The applicant notes the analyses with drug charges removed were likely an over-estimation of the ancillary drug charges that would be removed in cases involving the use of Casgevy™, but these were provided as sensitivity analyses.

According to the applicant, eligible cases for Casgevy™ will be mapped to either Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) or Pre-MDC MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC), depending on whether complications or comorbidities (CCs) or major complications or comorbidities (MCCs) are present. For each analysis, the applicant used the FY 2025 new technology add-on payment threshold for Pre-MDC MS–DRG 016 for all identified cases, because it was typically higher than the threshold for Pre-MDC MS–DRG 017. Each analysis followed the order of operations described in the table later in this section.

For the first cohort, the applicant included all cases associated with MS–DRG 014 (Allogeneic Bone Marrow Transplant). The applicant used the inclusion/exclusion criteria described in the following table and identified 996 claims mapping to MS–DRG 014. With all prior drug charges maintained (Scenario 1), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,325,062, which exceeded the average case-weighted threshold amount of $182,491. With all prior drug charges removed (Scenario 2), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,181,526, which exceeded the average case-weighted threshold amount of $182,491.

For the second cohort, the applicant searched for cases within MS–DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD–10–CM diagnosis codes representing SCD or TDT. The applicant used the inclusion/exclusion criteria described in the following table and identified 11 claims mapping to MS–DRG 014 (Allogeneic Bone Marrow Transplant). With all prior drug charges maintained (Scenario 3), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,125,212, which exceeded the average case-weighted threshold amount of $182,491. With all prior drug charges removed (Scenario 4), the applicant calculated a final inflated average case-weighted standardized charge per case of $12,086,551, which exceeded the average case-weighted threshold amount of $182,491.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that Casgevy™ meets the cost criterion.

CASGEVY™ COST ANALYSIS[21]	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for Casgevy™.
List of MS-DRGs	014 (Allogeneic Bone Marrow Transplant with CC/MCC)
Inclusion/ exclusion criteria	Cohort 1: The applicant included all cases assigned to MS-DRG 014 (Allogeneic Bone Marrow Transplant). Cohort 2: The applicant searched for cases within MS-DRG 014 (Allogeneic Bone Marrow Transplant) with any ICD-10-CM diagnosis codes representing SCD or TDT using the codes listed in the online posting for Casgevy™.
Charges removed for prior technology	Scenarios 1 and 3 (the first scenario of each cohort): The applicant removed 100% of charges associated with allogeneic bone marrow transplants, as treatment with Casgevy™ would eliminate the need for an allogeneic hematopoietic stem cell transplant (allo-HSCT). The applicant did not remove any indirect charges related to ancillary drugs. Scenarios 2 and 4 (the second scenario of each cohort): The applicant removed 100% of charges associated with allogeneic bone marrow transplants, as treatment with Casgevy™ would eliminate the need for an allo-HSCT. The applicant removed all indirect charges related to ancillary drugs.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.9% to the standardized charges, based on the two-year inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

[21] Lists referenced here may be found in the cost criterion codes and MS-DRGs attachment included in the online posting for the technology.

We are inviting public comments on whether Casgevy™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Casgevy™ represents a substantial clinical improvement over existing technologies because it is expected to avoid certain serious risks or side effects associated with the existing approved gene therapy for TDT, Zynteglo™. The applicant provided one study to support these claims, as well as two package inserts.[22] The following table summarizes the applicant's assertion regarding the substantial clinical improvement criterion. Please see the online posting for Casgevy™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available.	
Applicant statements in support	**Supporting evidence provided by the applicant**
Casgevy™ is expected to avoid certain serious risks or side effects associated with approved viral-based gene therapies for TDT.	CASGEVY (exagamglogene autotemcel) [package insert]. Boston, MA: Vertex Pharmaceuticals, Inc.; 2023. Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

After review of the information provided by the applicant, we have the following concerns regarding whether Casgevy™ meets the substantial clinical improvement criterion. We note that the provided evidence did not include any peer-reviewed literature that directly assessed the use of Casgevy™ for TDT. We note that the only assessment of the technology submitted was from a conference presentation [23] that provides data on the CLIMB–111 trial, an ongoing phase 1/2/3 single-arm trial assessing a single dose of Casgevy™ in patients 12 to 35 years old with TDT. The data submitted by the applicant indicated 48 participants aged 12 to 35 years received Casgevy™ for TDT, of which only 27 participants were evaluable for the primary and key secondary endpoints because they were followed for at least 16 months (up to 43.7 months) after Casgevy™ infusion. Per the applicant's conference presentation, 88.9% of participants achieved both the primary efficacy endpoint (transfusion independence for 12 consecutive months while maintaining a weighted average hemoglobin of at least 9 g/dL) and the key secondary efficacy endpoint (transfusion independence for 6 consecutive months while maintaining a weighted average hemoglobin of at least 9 g/dL). The applicant noted that two patients had serious adverse events related to Casgevy™. Due to the small study population and the median age of participants in the study, we question if these study outcomes would be generalizable to a Medicare population. In addition, from the evidence submitted, we were also unable to determine where the study took place (that is, within the U.S. or in locations outside the U.S), which may also limit generalizability to the Medicare population. We also question if the short follow-up duration is sufficient to assess improvements in long-term clinical outcomes.

Furthermore, with regard to the claim that Casgevy™ is expected to avoid certain serious risks or side effects associated with approved viral-based gene therapies for TDT, the applicant stated that Zynteglo™ utilizes gene transfer to use a modified, inert lentivirus to add working exogenous copies of the β-globin gene to increase functional hemoglobin A; due to this mechanism of action and the semi-random nature of viral integration, the applicant stated that treatment with Zynteglo™ carries the risk of lentiviral vector (LVV)-mediated insertional oncogenesis after treatment. The applicant explained that Casgevy™ is an autologous ex-vivo modified hematopoietic stem-cell biological product which uses a non-viral mechanism of action (CRISPR/Cas9 gene editing), and therefore, this technology does not carry a risk for insertional oncogenesis. The applicant also noted that gene editing approaches, including CRISPR/Cas9, have the potential to produce off-target edits, but in trials to date, off-target gene editing has not been observed in the edited CD34+ cells from healthy donors or patients. We note that we are unclear regarding the frequency and related clinical relevance of LVV-mediated oncogenesis. We also question if the follow-up duration for patients treated with Casgevy™ is sufficient to assess improvement in the rate of malignancy. We would be interested in more information on the overall safety profile comparison between Casgevy™ and Zynteglo™, as well as any comparisons of Casgevy™ to another potentially curative treatment, allogeneic hematopoietic stem cell transplant for patients with TDT.

We are inviting public comments on whether Casgevy™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Casgevy™.

c. DuraGraft® (Vascular Conduit Solution)

Marizyme, Inc. submitted an application for new technology add-on payments for DuraGraft® for FY 2025. According to the applicant, DuraGraft® is an intraoperative vein-graft preservation solution used during the harvesting and grafting interval during coronary artery bypass graft surgery (CABG). The applicant stated that the use of DuraGraft® does not change clinical/surgical practice; it replaces solutions currently used for flushing and storage of the saphenous vein grafts (SVG) from harvesting through grafting, including tests for graft leakage. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26795), Somahlution, Inc., acquired by Marizyme in 2020,[24] submitted and

[22] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[23] Locatelli F, et al. Presented at the 28th Annual European Hematology Association; 11 June 2023.

[24] NASDAQ. Marizyme, Inc. Completes Acquisition of Somahlution, Inc. and Raises $7.0 Million in Private Placement | Nasdaq (accessed 1/23/2023).

withdrew applications for new technology add-on payments for DuraGraft® for FY 2018 and FY 2019. The applicant also submitted an application for new technology add-on payments for FY 2020, as summarized in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19305 through 19312), that it withdrew prior to the issuance of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42180). We note that the applicant also submitted an application for new technology add-on payments for FY 2024, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26795 through 26803), that it withdrew prior to the issuance of the FY 2024 IPPS/LTCH PPS final rule (88 FR 58804).

Please refer to the online application posting for DuraGraft®, available at *https://mearis.cms.gov/public/publications/ntap/NTP231012EE9NW,* for additional detail describing the technology and intraoperative ischemic injury.

With respect to the newness criterion, according to the applicant, DuraGraft® was granted De Novo classification from FDA on October 4, 2023, for adult patients undergoing Coronary Artery Bypass Grafting surgeries and is intended for flushing and storage of SVGs from harvesting through grafting for up to 4 hours. Per the applicant, DuraGraft® is not yet commercially available due to a delay related to finalizing the label prior to manufacturing.

The applicant stated that effective October 1, 2017, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of DuraGraft®: XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3). Please refer to the online application posting for the complete list of ICD–10–CM and PCS codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that DuraGraft® is not substantially similar to other currently available technologies because DuraGraft® is a first-in-class product as a storage and flushing solution for vascular grafts used during CABG surgery and the components of DuraGraft® directly interfere with the mechanisms of oxidative damage, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for DuraGraft® for the applicant's complete statements in support of its assertion that DuraGraft® is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	DuraGraft® is a first-in-class product and there is no product that is similar. Common storage solutions are only salt solutions and have no ability to protect against oxidative damage and metabolic stress which are the primary mechanisms associated with ischemic injury. They are used to keep the graft wet. DuraGraft® has been formulated into a wetting solution. DuraGraft® treatment is associated with a reduction in both vein graft disease and clinical complications associated with vein graft failure post-CABG. There are currently no commercial products that prevent ischemic injury of vein grafts during CABG surgery or products that reduce vein graft disease or its complications following CABG surgery.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	MS-DRGs used during CABG surgery are aligned to the same MS-DRGs for which DuraGraft® use is indicated.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	DuraGraft® is used in the CABG patient population.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26796), we expressed concern that the mechanism of action of DuraGraft® may be the same or similar to other vein graft storage solutions. Similarly, we note that according to the applicant, DuraGraft® prevents intraoperative ischemic injury to the endothelial layer of free vascular grafts, reducing the risks for post-CABG vein graft disease and graft failure, which are clinical manifestations of graft ischemia reperfusion injury (IRI), and we question whether DuraGraft® might have a similar mechanism of action as existing treatments for preventing ischemic injury of vein grafts during CABG surgery and reducing vein graft disease or its complications following CABG surgery. We are inviting public comments on whether DuraGraft® is substantially similar to existing technologies and whether DuraGraft® meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for DuraGraft®, the applicant searched the FY 2022 MedPAR file for cases reporting a combination of ICD–10–CM/PCS codes that represent patients who underwent CABG procedures. Please see the online posting for DuraGraft® for a complete list of MS–DRGs and ICD–10–CM and PCS codes provided by the applicant. Using the inclusion/exclusion criteria described in the following table, the applicant identified 33,511 cases mapping to 59 MS–DRGs, including MS–DRG 236 (Coronary Bypass Without Cardiac Catheterization Without MCC) representing 21.9 percent of the identified cases. The applicant followed the order of operations described in the following table and

calculated a final inflated average case-weighted standardized charge per case of $321,620, which exceeded the average case-weighted threshold amount of $235,829. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that DuraGraft® meets the cost criterion.

DURAGRAFT® COST ANALYSIS[25]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for DuraGraft®.
List of ICD-10-PCS codes	For the list of ICD-10-PCS codes, see the online posting for DuraGraft®.
List of MS-DRGs	For the list of MS-DRGs, see the online posting for DuraGraft®.
Inclusion/exclusion criteria	The applicant identified cases by using a combination of ICD-10-CM/PCS codes provided by the applicant in the online posting that represent patients who underwent CABG procedures. The applicant excluded cases with the ICD-10-PCS code XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3). Per the applicant, DuraGraft® is first in class product and there is no product that is similar. The applicant stated that since DuraGraft® is the only product that is described by this code and it is not on the market yet, there is no procedure at this time for which this code should be reported.
Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.303 for supplies and equipment from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We note the following concerns regarding the cost criterion. Although the applicant did not remove direct or indirect charges related to the prior technology, we note that the applicant indicated that the use of DuraGraft® replaces solutions currently used for flushing and storage of the SVGs harvested through grafting, including tests for graft leakage, in its discussion of the newness criterion. Therefore, we question whether the cost criterion analysis should remove charges for related or prior technologies, such as autologous heparinized blood (AHB), Plasmalyte/Normosol, Lactated Ringers, and heparinized saline (HS).

We are inviting public comments on whether DuraGraft® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that DuraGraft® represents a substantial clinical improvement over existing technologies because there is no other product or technology that reduces the incidence of peri-operative myocardial infarction. The applicant provided four studies to support this assertion, as well as 47 background articles about reducing major adverse cardiac events (MACE).[26] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for DuraGraft® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[25] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

[26] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available.	
Applicant statements in support	**Supporting evidence provided by the applicant**
Reduced Long-term Repeat Revascularization	Haime, M, McLean RR, and Kurgansky KE, et al (2018). Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting. *Expert Review of Cardiovascular Therapy*, 16:12, 963-970. DOI: 10.1080/14779072.2018.1532289 Lopez-Menendez J, Castro-Pinto M, and Fajardo E, Miguelena J, et al. Vein graft preservation with an endothelial damage inhibitor in isolated coronary artery bypass surgery: an observational propensity score-matched analysis. *J Thorac Dis* 2023;15(10):5549-5558. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduction in Acute Coronary Syndrome (ACS) Requiring Hospitalization	Lopez-Menendez (2023) *op.cit.* pp. 5549-5558.
Reduced Peri-operative Myocardial Infarction (MI)	Haime (2018). *op.cit.* pp. 963-970. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Improve Myocardial Protection	Szalkiewicz, P, Emmert, MY, and Heinisch, PP, et al (2022). Graft Preservation confers myocardial protection during coronary artery bypass grafting. *Frontiers in Cardiovascular Medicine*, July 2022, pp 1-10. DOI 10.3389/fcvm.2022.922357 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduced Mortality Through 3 Years Follow-up post-CABG	Marizyme. Internal Study Report. Safety of DuraGraft: A Comparison to Standard of Care Graft Storage Solutions in Isolated CABG Patients in the Largest Worldwide CABG Registry 3-Year Follow-up Post-Market DuraGraft® Registry vs. Standard of Care CABG in the STS Database. Unpublished manuscript. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Significantly Reduced Maximum (Peak) Values of Troponin	Szalkiewicz (2022) *op.cit.* p. 1-10. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduced 12mo. Overall Mean Wall Thickness (Whole Graft Analysis)	Perrault, LP, Carrier, M, and Voisine, P, et al (2021). Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting. *Journal of Thoracis and Cardiovascular Surgery*. Jan. 2021, Vol. 161, Number 1, 96-106. https://doi.org/10.1016/j.jtcvs.2019.10.115 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduced Long-term Non-fatal MI	Haime (2018). *op.cit.* pp. 963-970. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Decreased Rate of Change from 1-12 months for Maximum Graft Narrowing (Focal Stenosis)	Perrault (2021) *op.cit.* pp. 96-106. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduced Long-term MACE	Lopez-Menendez (2023) *op.cit.* pp. 5549-5558. Haime (2018) *op.cit.* pp. 963-970. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Significantly Reduced Median Area Under the Curve (AUC) for Troponin-I	Szalkiewicz (2022) *op.cit.* pp. 1-10. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Troponin-I Values Significantly Decreased from 3-6 hours up to 4 days post-CABG in DuraGraft® Group	Szalkiewicz (2022) *op.cit.* pp. 1-10. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

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After review of the information provided by the applicant, we have the following concerns regarding whether DuraGraft® meets the substantial clinical improvement criterion. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26800 through 26801), we expressed concern regarding the relatively small sample sizes of the Szalkiewicz et al. (2022) [27] and Perrault et al. (2021) [28] studies, as compared to the number of potentially eligible patients for this technology, and relatively short follow-up periods. We continue to question whether the sample was representative of the number of Medicare beneficiaries potentially eligible for DuraGraft®. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule for further discussion of these concerns. For its FY 2025 application, the applicant also cited Lopez-Menendez et al. (2021),[29] which we note used a sample size of 180, and therefore we similarly question whether

[27] Szalkiewicz, P, Emmert, MY, and Heinisch, PP, et al (2022). Graft Preservation confers myocardial protection during coronary artery bypass grafting. *Frontiers in Cardiovascular Medicine,* July 2022, pp 1–10. *DOI 10.3389/fcvm.2022.922357.*

[28] Perrault, LP, Carrier, M, and Voisine, P, et al (2021). Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting. *Journal of Thoracis and Cardiovascular Surgery*. Jan. 2021, Vol. 161, Number 1, 96–106. *https://doi.org/10.1016/j.jtcvs.2019.10.115.*

[29] Lopez-Menendez J, Castro-Pinto M, and Fajardo E, Miguelena J, et al. Vein graft preservation with an endothelial damage inhibitor in isolated coronary artery bypass surgery: an observational propensity score-matched analysis. *J Thorac Dis* 2023;15(10):5549–5558.

the results of this study would be replicated with a larger patient sample.

In the FY 2024 IPPS/LTCH proposed rule (88 FR 26800 through 26801), we also questioned whether the results from the Haime et al. (2018) [30] study could be generalized to other patient groups, including nonveterans, women, or those from other racial or ethnic groups. We continue to question whether the demographic profiles in the Perrault, Szalkiewicz, and Haime studies that the applicant submitted were comparable with those of the U.S. Medicare patients who underwent CABG surgery. For its FY 2025 application, the applicant also cited the Lopez-Menendez et al. (2021) [31] study, which was based on a European patient population that was predominantly male (82 percent to 90 percent). However, as we noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26800 through 26801), among the Medicare fee-for-service beneficiaries who underwent CABG surgery, male patients accounted for two-thirds (66 percent) of this population. Therefore, we continue to question whether the findings of these studies would be replicable among the Medicare population.

We are inviting public comments on whether DuraGraft® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for DuraGraft®.

Comment: The applicant submitted a public comment in response to our question as to why two propensity match models were used in the propensity match comparison of the EU DuraGraft® Registry to the STS Registry that it presented during the New Technology Town Hall meeting. The applicant explained that the goal of propensity matching was to balance patient and technical factors predictive of mortality throughout the observation period and to correct for differences that may be encountered in the U.S. and Europe. The applicant stated that a primary propensity score model (PSM) with 35 variables (2,400 patients matched), and a secondary PSM with 25 variables (2,522 patients matched, sensitivity analysis) were used. The applicant noted that the propensity variables were chosen with a goal of comparing variables descriptive of (1) U.S. and Western European populations, (2) the general practice of cardiac surgery, and (3) standards of care for surgical technique. The applicant noted that an important set of variables that needed to be balanced were the components of the EuroScore II (ESII). ESII is comprised of 18 patient variables and, per the applicant, is considered to be the best predictor of peri-operative and early mortality. ESII variables relevant for shorter term mortality were supplemented with appropriate predictors for longer term mortality.[32] [33] [34]

The applicant noted that the set of variables for the primary PSM included 35 characteristics that are most strongly associated with mortality across the time periods (including 1-year post-CABG) and were consistently observed to have the highest degree of impact in the studies. The applicant stated that these variables include demographics, cardiac and pre-op surgical risk factors, coronary anatomy, and surgical/procedural key characteristics (for example, grafting strategy and conduit selection) to serve as the primary analysis. The applicant indicated that all characteristics in the ESII are included in the risk factors, with the exception of endocarditis, surgery on the thoracic aorta, weight of the intervention, and poor mobility, as they are not relevant to the subset of patients being propensity matched, or in the case of poor mobility, not collected in both databases. The applicant stressed that this list was reviewed and edited with FDA during the pre-submission process. To further allow for the selection of a cohort matched for standard of care and surgical technique between the European and U.S. populations, additional relevant variables were added including pre-op cardiac risk, coronary anatomy, and surgical technique.

The applicant further noted that the set of variables for the secondary PSM included 25 of the 35 variables from the primary PSM, excluding characteristics of pre-op cardiac risk factors, coronary anatomy, and aspects of surgical technique. The applicant asserted that the secondary PSM serves as a sensitivity analysis to estimate whether the standard of care for the treatment of patients with advanced coronary artery disease and surgical techniques differ for patients in the two cohorts which are otherwise balanced for surgical risk factors, and whether these differences could affect mortality outcomes.

Response: We thank the applicant for its comments. We also note that the applicant has provided the baseline demographic characteristics and surgical risk factors of the two cohorts before and after propensity score matching, which appears to demonstrate that the two cohorts were more similar in those characteristics and factors as a result of propensity score matching. We will take this information into consideration when deciding whether to approve new technology add-on payments for DuraGraft®.

d. ELREXFIO™ (elranatamab-bcmm)

Pfizer, Inc. submitted an application for new technology add-on payments for ELREXFIO™ for FY 2025. According to the applicant, ELREXFIO™ is a B-cell maturation antigen (BCMA) directed cluster of differentiation (CD)3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (mAb). Per the applicant, ELREXFIO™ is a bispecific, humanized immunoglobulin 2-alanine (IgG2Δa) kappa antibody derived from two mAbs, administered as a fixed-dose, subcutaneous treatment. We note that the applicant submitted an application for new technology add-on payments for ELREXFIO™ for FY 2024 under the name elranatamab, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26803 through 26809), but the technology did not meet the July 1, 2023 deadline for FDA approval or clearance of the technology and,

[30] Haime, M, McLean RR, and Kurgansky KE, et al (2018). Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting, *Expert Review of Cardiovascular Therapy,* 16:12, 963–970. *DOI: 10.1080/14779072.2018.1532289.*

[31] Ibid.

[32] Aldea, G.S., Bakaeen, F.G., Pal, J., Fremes, S., Head, S.J., Sabik, J., Rosengart, T., Kappetein, A.P., Thourani, V.H., Firestone, S., Mitchell, J.D., & Society of Thoracic Surgeons (2016). The Society of Thoracic Surgeons Clinical Practice Guidelines on Arterial Conduits for Coronary Artery Bypass Grafting. *The Annals of thoracic surgery,* 101(2), 801–809. *https://doi.org/10.1016/j.athoracsur.2015.09.100.*

[33] Kolh, P., Kurlansky, P., Cremer, J., Lawton, J., Siepe, M., & Fremes, S. (2016). Transatlantic Editorial: A Comparison Between European and North American Guidelines on Myocardial Revascularization. *The Annals of thoracic surgery,* 101(6), 2031–2044. *https://doi.org/10.1016/j.athoracsur.2016.02.062.*

[34] Shahian, D.M., O'Brien, S.M., Sheng, S., Grover, F.L., Mayer, J.E., Jacobs, J.P., Weiss, J.M., Delong, E.R., Peterson, E.D., Weintraub, W.S., Grau-Sepulveda, M.V., Klein, L.W., Shaw, R.E., Garratt, K.N., Moussa, I.D., Shewan, C.M., Dangas, G.D., & Edwards, F.H. (2012). Predictors of long-term survival after coronary artery bypass grafting surgery: results from the Society of Thoracic Surgeons Adult Cardiac Surgery Database (the ASCERT study). *Circulation,* 125(12), 1491–1500. *https://doi.org/10.1161/CIRCULATIONAHA.111.066902.*

therefore, was not eligible for consideration for new technology add-on payments for FY 2024 (88 FR 58804).

Please refer to the online application posting for ELREXFIO™ available at *https://mearis.cms.gov/public/publications/ntap/NTP2310176PV9B,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, ELREXFIO™ was granted Biologics License Application (BLA) approval from FDA on August 14, 2023, for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb. According to the applicant, ELREXFIO™ was commercially available immediately after FDA approval. Per the applicant, the recommended doses of ELREXFIO™ subcutaneous injection are step-up doses of 12 mg on day 1 and 32 mg on day 4, followed by a first treatment dose of 76 mg on day 8 and subsequent treatment doses as indicated in the label. The applicant noted that treatment doses may be administered in an inpatient or outpatient setting. Per the applicant, patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose. The applicant assumed that there would be a single inpatient stay, with one 44 mg vial used per dose, resulting in two doses (each a step-up dose) being administered.

The applicant stated that effective October 1, 2023, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of ELREXFIO™: XW013L9 (Introduction of elranatamab antineoplastic into subcutaneous tissue, percutaneous approach, new technology group 9). The applicant stated that C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), C90.02 (Multiple myeloma in relapse), and Z51.12 (Encounter for antineoplastic immunotherapy) may be used to currently identify the indication for ELREXFIO™ under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that ELREXFIO™ is not substantially similar to other currently available technologies because it is the only therapy approved for the treatment of patients with RRMM who have received 4 prior lines of therapy including a PI, IMiD, and mAb that uses a humanized IgG2a antibody for the mechanism of action. Per the applicant, it is also the only BCMA-directed bispecific antibody (bsAb) therapy with clinical study data in its prescribing information supporting use in patients who have received prior BCMA-directed therapy, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for ELREXFIO™ for the applicant's complete statements in support of its assertion that ELREXFIO™ is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	ELREXFIO™ does not use the same or similar mechanism of action as any other therapy because it has a different protein sequence and molecular structure from other therapies. There are currently three bsAb therapies approved for this patient population: ELREXFIO™, TECVAYLI®, AND TALVEY™. For ELREXFIO™, the two targets are BCMA on the myeloma cancer cell and CD3 on the tumor killing T-cell. In addition to the bsAb targets, the mechanism of action is also influenced by the antibody structure, including the antibody constant IgG regions. ELREXFIO™ is currently the only BCMA-directed bsAb therapy that uses a humanized IgG2Δa kappa antibody backbone. Of the four human IgG isotypes, human IgG2 antibodies have the lowest overall level of effector function, as they only weakly induce complement and cell activation due to low affinity for human complement proteins (C1q) and immune cell receptors (Fcγ receptors). Having a low level of effector function in the IgG region is key to the mechanism of these molecules. This means the antibody should activate T-cells only in the presence of BCMA, which is highly expressed on tumor cells. Having these changes in the molecule to lower effector function means it should only stimulate an immune response in the tumor. A different IgG backbone, for example an IgG4, that has a high effector function could stimulate a bigger immune response and increased inflammation which may mean increased risk of immune-mediated toxicities. TECVAYLI® uses an IgG4 antibody backbone, which has a high affinity for Fc gamma receptor subtype I but weak affinities for all other Fc gamma receptor subtypes and are poor inducers of Fc-mediated effector functions. ELREXFIO™ also has a unique complementarity-determining region (CDR) sequence, which is the region of antibody that recognizes and binds to target epitopes. The CDR is critical to the mechanism of action of bsAb therapy because it results in different targeted regions, which impacts how the drug works to target the cancer cells.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	It is unclear to which MS-DRG the ICD-10-PCS code for administration of ELREXFIO™ (XW013L9) has been assigned as we were unable to identify the assignment in the current MS-DRG Grouper (version 41) on the CMS website. However, we believe that RRMM patients treated with a bsAb therapy, such as TECVAYLI®, ELREXFIO™, or TALVEY™, who have received at least four prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb will have a diagnosis code that is assigned to MS-DRG 840, 841, 842, 846, 847, or 848.

Does use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	ELREXFIO™ does not involve treatment of the same or similar type of patient population when compared to existing therapies because it is the only BCMA-directed CD3 T-cell engager that includes in its FDA-approved prescribing information clinical study data supporting its use in RRMM patients who received prior BCMA-directed therapy. There are three bsAb therapies, including ELREXFIO™, that are generally indicated for the treatment of adult patients with RRMM who have received at least four prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb. Two of those, ELREXFIO™ and TECVAYLI®, are BCMA-directed therapies. However, of the two, ELREXFIO™ is the only therapy for which the FDA included clinical study data in section 14 of the prescribing information describing efficacy and safety in a patient population that had received prior BCMA-directed therapy. The inclusion of clinical study data on the prior BCMA-exposed patient population in the prescribing information is important because patients who have received prior BCMA-directed therapy have generally received more prior lines of therapy. For example, in MagnetisMM-3, prior BCMA exposed patients had received a median of eight prior lines of therapy (the range being 4-19). Even though the indications for use for ELREXFIO™ are the same as that for TECVAYLI® and TALVEY™, the inclusion of clinical study data is helpful for informing the use of ELREXFIO™ in this particular patient population in addition to treatment of patients without prior BCMA-directed therapy.

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With regard to the newness criterion, similar to our discussion in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26804), we note that ELREXFIO™ may have a similar mechanism of action to that of TECVAYLI®, for which we approved an application for new technology add-on payments for FY 2024 (88 FR 58891) for the treatment of adult patients with RRMM after four or more prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb. As we previously noted, TECVAYLI®'s mechanism of action is described as a bsAb, with binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor (88 FR 58886). The applicant asserts that ELREXFIO™ has a unique CDR (the region of antibody that recognizes and binds to target epitopes) that is critical to the mechanism of action because it results in different targeted regions, impacting how the drug works to target the cancer cells. However, it is unclear how these differences result in a substantially different mechanism of action from TECVAYLI®. Because of the apparent similarity with the bsAb for ELREXFIO™ that uses binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor, we believe that the mechanism of action for ELREXFIO™ may be the same or similar to that of TECVAYLI®. The applicant also asserts that ELREXFIO™ is different from TECVAYLI® because the two are based on different immunoglobulin isotypes, and with the lower effector function of IgG2, ELREXFIO™ should only activate T-cells in the presence of BCMA and thus should only stimulate an immune response in the tumor. Based on our understanding, however, that this may relate to the risk of adverse event from ELREXFIO™ administration but is not critical to the way the drug treats the underlying disease, we question whether this would therefore relate to an assessment of substantial clinical improvement, rather than of substantial similarity.

We also note that ELREXFIO™ and TECVAYLI® may treat the same or similar disease (RRMM) in the same or similar patient population (patients who have previously received a PI, IMiD, and an anti-CD38 mAb). The applicant claims ELREXFIO™ is different from TECVAYLI® because the prescribing information includes a new subpopulation, the patient population that had received prior BCMA-directed therapy. However, we believe the lack of inclusion of this population in the prescribing information for TECVAYLI® does not necessarily exclude the use of TECVAYLI® in this patient population, nor does the FDA prescribing information for TECVAYLI® specifically exclude this patient population. As such, it is unclear whether ELREXFIO™ would in fact treat a patient population different from TECVAYLI®. Accordingly, as it appears that ELREXFIO™ and TECVAYLI® may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if we determine that this technology is substantially similar to TECVAYLI®, we believe the newness period for this technology would begin on November 9, 2022, the date TECVAYLI® became commercially available.

Furthermore, we believe another applicant for FY 2025 new technology add-on payments, TALVEY™, may also be substantially similar to ELREXFIO™. Per the application for TALVEY™, TALVEY™ is a bispecific antibody approved for the treatment of adults with RRMM who have received at least four prior lines of therapy, including a PI, IMiD, and an anti-CD38 monoclonal antibody. The applicant for TALVEY™ states TALVEY™ recruits CD3-expressing T cells to myeloma cells that express GPRC5D, resulting in activation of the T cell receptor pathway and lysis of GPRC5D-expressing MM cells. Per the applicant for TALVEY™, TALVEY™ was available for sale immediately after its approval on August 9, 2023. We

believe TALVEY™ may be substantially similar to ELREXFIO™ because it is also a bispecific antibody that treats RRMM in patients who have previously received a PI, IMiD, and an anti-CD38 mAb. Additionally, we note that similar to ELREXFIO™, the prescribing information for TALVEY™ includes the population with prior exposure to BCMA T-cell redirection therapy. Accordingly, as it appears that ELREXFIO™ and TALVEY™ would use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and would treat the same or similar disease in the same or similar patient population, we believe that these technologies may also be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We note that if ELREXFIO™ is determined to only be substantially similar to TALVEY™, and not TECVAYLI®, we believe the newness period for ELREXFIO™ would begin on August 9, 2023, the date TALVEY™ received FDA approval.

We are interested in receiving information on how these technologies may differ from each other with respect to the substantial similarity and newness criteria, to inform our analysis of whether ELREXFIO™ is substantially similar to TALVEY™ and/or TECVAYLI®.

We are inviting public comments on whether ELREXFIO™ is substantially similar to existing technologies and whether ELREXFIO™ meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for ELREXFIO™, the applicant searched the FY 2022 MedPAR for cases reporting one of the following ICD–10–CM codes in any position: C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), or C90.02 (Multiple myeloma in relapse). Using the inclusion/exclusion criteria described in the following table, the applicant identified 4,689 claims mapping to five MS–DRGs: MS–DRGs 840, 841, and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 846 and 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC and with CC, respectively). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $170,699, which exceeded the average case-weighted threshold amount of $77,190. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that ELREXFIO™ meets the cost criterion.

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ELREXFIO™ COST ANALYSIS	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	C90.00 (Multiple myeloma not having achieved remission) C90.01 (Multiple myeloma in remission) C90.02 (Multiple myeloma in relapse)
List of MS-DRGs	840 (Lymphoma and Non-Acute Leukemia with MCC) 841 (Lymphoma and Non-Acute Leukemia with CC) 842 (Lymphoma and Non-Acute Leukemia without CC/MCC) 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC)
Inclusion/exclusion criteria	The applicant identified cases reporting the ICD-10-CM codes in this table in any diagnosis position that were assigned to one of the MS-DRGs listed in this table. Per the applicant, MS-DRGs 840, 841, 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC, and without CC/MCC respectively) were selected because patients with a primary diagnosis of multiple myeloma and receiving chemotherapy treatment could be assigned to these MS-DRGs. MS-DRGs 846, 847, or 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC, with CC, and without CC/MCC, respectively) were selected by the applicant because cases reporting the administration of chemotherapy/immunotherapy with a secondary diagnosis of multiple myeloma would be assigned to these MS-DRGs. Managed care cases, claims submitted only for graduate medical education payments, claims with ancillary costs of zero and claims that were statistical outliers within the MS-DRG were excluded. The applicant did not identify any cases with a diagnosis of multiple myeloma in the FY 2022 MedPAR file analysis that were grouped to MS-DRG 848. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	Per the applicant, ELREXFIO™ would replace current chemotherapy, and patients would continue to receive other drugs (for example antiemetics). To be conservative, the applicant removed 80% of drug charges since it could not separate out the type of drugs in the drug charges. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.18 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant added indirect charges related to use of the new technology for routine care, as the length of stay would be at least 5 days for all cases receiving ELREXFIO™. The applicant calculated charges for routine care in accordance with the prescribing information and assumed the two step-up doses of ELREXFIO™ must both be received under inpatient care. The applicant estimated the average standardized charge per day of routine care by summing standardized charges billed to the routine care cost center and length of stay across all cases that met the selection criteria. The sum of routine care charges was divided by the sum of length of stay days, for each MS-DRG. The average number of days short of a 5-day stay and the proportion of stays less than 5 days long was calculated, for each MS-DRG. The applicant multiplied the average standardized routine care charge per day by the proportion of stays less than 5 days and by the average days short of a 5-day stay, for each MS-DRG.

We are inviting public comments on whether ELREXFIO™ meets the cost criterion.

With regards to the substantial clinical improvement criterion, the applicant asserted that ELREXFIO™ represents a substantial clinical improvement over existing technologies because it is a new treatment option for late-line RRMM patients who are refractory to or otherwise ineligible for existing therapy. Per the applicant, it significantly improves outcomes compared to existing therapy (Cohort A objective response rate (ORR) of 57.7 percent with a complete response (CR) or better achieved in 25.8 percent and very good partial response (VGPR) in 25.8 percent; Cohort B ORR of 33.3 percent with duration of response (DOR) of 84.3 percent at 9 months), has a manageable safety profile, and shorter hospitalization than TECVAYLI® and TALVEY™. The applicant provided nine studies assessing ELREXFIO™ to support these claims, as well as 12 background articles about RRMM and comparator technologies.[35] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for ELREXFIO™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[35] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
ELREXFIO™ is a new treatment option for late-line patients with RRMM who are refractory to existing therapies or otherwise ineligible for or unable to access them.	ELREXFIO™ (elranatamab-bcmm) injection, for subcutaneous use; Pfizer Laboratories Division Pfizer Inc., 2023. Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: Phase 2 MagnetisMM-3 trial results. Nat Med. 2023 Aug 15. Online ahead of print. Nooka, A. K., Lesokhin, A. M., Mohty, M., Niesvizky, R., Maisel, C., Arnulf, B., Larson, S. M., Varshavsky Yanovsky, A., Leleu, X. P., & Karlin, L. (2023). Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma (RRMM) and prior B-cell maturation antigen (BCMA)-directed therapies: A pooled analysis from MagnetisMM studies. 2023 ASCO Annual Meeting.
ELREXFIO™ is the only BCMA-directed bispecific that contains clinical study data in the prescribing information to support use in patients who have been treated with a prior BCMA-directed therapy.	ELREXFIO™ (elranatamab-bcmm) injection, for subcutaneous use; Pfizer Laboratories Division Pfizer Inc., 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
CAR T-cell therapies are largely unavailable to Medicare beneficiaries with late-line RRMM.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Multiple Myeloma is an incurable malignancy and the ability of a patient to respond to therapy and the amount of time spent in response shortens and patients run out of therapy options to control their disease.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
In addition to being efficacious, ELREXFIO™ has a generally manageable safety profile without dysgeusia and other toxicities that severely impact quality of life.	ELREXFIO™ (elranatamab-bcmm) injection, for subcutaneous use; Pfizer Laboratories Division Pfizer Inc., 2023. Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: Phase 2 MagnetisMM-3 trial results. Nat Med. 2023 Aug 15. Online ahead of print. Nooka, A. K., Lesokhin, A. M., Mohty, M., Niesvizky, R., Maisel, C., Arnulf, B., Larson, S. M., Varshavsky Yanovsky, A., Leleu, X. P., & Karlin, L. (2023). Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma (RRMM) and prior B-cell maturation antigen (BCMA)-directed therapies: A pooled analysis from MagnetisMM studies. 2023 ASCO Annual Meeting. Tomasson MH, et al., Long-Term Efficacy and Safety of Elranatamab Monotherapy in the Phase 2 MagnetisMM-3 Trial in Relapsed or Refractory Multiple Myeloma. Oral presentation at: 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9-12. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

ELREXFIO™ significantly improves outcomes compared to existing therapies approved for late-line RRMM, including prior BCMA-exposed patients treated with a BCMA-directed bispecific antibody.	ELREXFIO™ (elranatamab-bcmm) injection, for subcutaneous use; Pfizer Laboratories Division Pfizer Inc., 2023. Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: Phase 2 MagnetisMM-3 trial results. Nat Med. 2023 Aug 15. Online ahead of print. Costa LJ, LeBlanc TW, Tesch H, et al. An indirect comparison of elranatamab's (ELRA) objective response rate (ORR) from MagnetisMM-3 (MM-3) versus real-world external control arms in triple-class refractory (TCR) multiple myeloma (MM). Presented at the European Hematology Association (EHA) Congress, 2023 June 8-11, Frankfurt, Germany. Costa LJ, et al., An Indirect Comparison of Elranatamab's Progression-Free Survival and Overall Survival from MagnetisMM-3 Versus Real-World External Control Arms in Triple-Class Refractory Multiple Myeloma. Abstract presented at the 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9-12. Hlavacek P, Mol I, Hu Y, et al. Indirect treatment comparison of elranatamab with belmaf, sel-dex, and real-world physician's choice of treatment in patients with triple-class exposed relapsed/refractory multiple myeloma. Presented at the European Hematology Association (EHA) Congress, 2023 June 8-11, Frankfurt, Germany. Jakubowiak A,Bahlis N, Raje N, et al, Elranatamab, a BCMA-Targeted T-Cell Redirecting Immunotherapy, for Patients with Relapsed or Refractory Multiple Myeloma: Updated Results From MagnetisMM-1. ASCO 2022. Nooka, A. K., Lesokhin, A. M., Mohty, M., Niesvizky, R., Maisel, C., Arnulf, B., Larson, S. M., Varshavsky Yanovsky, A., Leleu, X. P., & Karlin, L. (2023). Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma (RRMM) and prior B-cell maturation antigen (BCMA)-directed therapies: A pooled analysis from MagnetisMM studies. 2023 ASCO Annual Meeting. Isha Mol, et al., A Matching-Adjusted Indirect Comparison of the Efficacy of Elranatamab and Teclistamab in Patients with Triple-Class Exposed/Refractory Multiple Myeloma. Oral presentation at: 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9-12. Tomasson MH, et al., Long-Term Efficacy and Safety of Elranatamab Monotherapy in the Phase 2 MagnetisMM-3 Trial in Relapsed or Refractory Multiple Myeloma. Oral presentation at: 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9-12. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
ELREXFIO™ offers fewer hospitalization days during the step-up dosing period than other bispecific antibodies approved for patients with RRMM thus lowering barriers to patient access.	ELREXFIO™ (elranatamab-bcmm) injection, for subcutaneous use; Pfizer Laboratories Division Pfizer Inc., 2023. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

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After review of the information provided by the applicant, we have the following concerns regarding whether ELREXFIO™ meets the substantial clinical improvement criterion.

With respect to the claim ELREXFIO™ is a new treatment option for late-line patients with RRMM who are refractory to existing therapies or otherwise ineligible for or unable to access them, the applicant states the nature of the disease is such that patients typically become refractory to the available treatment options or patients may be unable to access some therapies for other reasons. The applicant further notes patients need new therapies with new mechanisms of action that can provide better efficacy, extend the duration of response, and be available to a larger subset of the late-line RRMM population, particularly patients with prior BCMA-directed therapy exposure. The applicant states that ELREXFIO™ addresses these limitations since it does not require patient-specific manufacturing and is the only BCMA-directed bispecific antibody therapy that has clinical study data on outcomes for patients exposed to prior BCMA-directed therapy in its prescribing information. We note the evidence presented does not identify a specific population that would benefit from ELREXFIO™ that would not be eligible for or benefit from other therapies for late-line RRMM, including TECVAYLI®, TALVEY™, CARVYKTI®, and ABECMA®. With regard to the population with prior BCMA-directed therapy exposure, as noted previously, the prescribing information for TALVEY™ also includes efficacy data in this population and the lack of inclusion of this population in the prescribing information for TECVAYLI® does not exclude the use of this drug for these patients.

With respect to the claim that ELREXFIO™ is the only BCMA-directed bispecific antibody with clinical study data in the prescribing information to support use in patients who have been treated with prior BCMA-directed therapy, the applicant states that although clinical studies evaluating TECVAYLI® included prior BCMA-exposed RRMM patients, in Section 14 of the prescribing information,[36] the

[36] TECVAYLI (teclistamab-cqyv), injection, for subcutaneous use; Janssen Biotech, Inc., 2023.

FDA-approved labeling does not acknowledge outcomes or safety data for prior BCMA-exposed patients. Furthermore, the applicant contends this lack of inclusion suggests that prior-BCMA exposed patients continue to have a high unmet need despite the availability of TECVAYLI®, and that the inclusion of this clinical study data in ELREXFIO™'s prescribing information suggests that ELREXFIO™ is able to fill this unmet need. However, as noted previously, the lack of inclusion of similar study data in TECVAYLI®'s prescribing information does not exclude the use of this drug in these patients. Additionally, TALVEY™ is a bsAb that was also studied in this patient population and has an indication for patients with prior BCMA-directed therapy.

With respect to the claim that CAR T-cell therapies are largely unavailable to Medicare beneficiaries with late-line RRMM, the applicant states CAR T-cells take a significant amount of time to manufacture, and given the rapid nature of RRMM, some patients may die or become ineligible for treatment by the time the CAR T-cells are available for infusion. However, we note that TECVAYLI® and TALVEY™ have also received FDA approval and would therefore be options for patients who are unable to access or receive CAR T-cell therapy.

The applicant states that MM is an incurable malignancy and that patients' ability to respond to therapy diminishes over time, leading to a reduced duration of response and eventually exhausting available therapy options to manage the disease. The applicant asserts that patients typically undergo several lines of therapy before exhausting therapy options and succumbing to the disease. The applicant references the low objective response rates (ORRs) of selinexor and conventional chemotherapy in RRMM patients. We note there are several treatments available to patients with RRMM who have received at least four prior lines of therapy including a PI, an IMiD, and an anti-CD38 mAb, such as TECVAYLI®, TALVEY™, ABECMA®, and CARVYKTI®. It is not clear from the evidence provided that there is a patient population eligible for and responsive to ELREXFIO™ that is neither eligible for nor responsive to any of these other available therapies.

The applicant further claims that ELREXFIO™'s generally manageable safety profile without dysgeusia and other toxicities that severely impact quality of life, in conjunction with the improved efficacy in late-line RRMM, makes it a substantial clinical improvement treatment over existing therapies. Additionally, the applicant asserts that dysgeusia and nail-related and skin-related toxicities that reduce quality of life with TALVEY™ are not reported with ELREXFIO™. However, the safety profile of ELREXFIO™ was not compared to ABECMA®, CARVYKTI®, or TECVAYLI®. We also note we did not receive evidence related to improved efficacy that compares ELREXFIO™ with ABECMA®, CARVYKTI®, TALVEY™, or TECVAYLI®, and we question if ELREXFIO™ improves efficacy relative to these other therapies.

With respect to the claim that ELREXFIO™ significantly improves outcomes compared to existing therapies approved for late-line RRMM, including prior BCMA-exposed patients, the applicant provides study results from MagnetisMM–3, an open-label, phase 2 study where after receiving two step-up priming doses, patients received subcutaneous ELREXFIO™ once weekly in 28-day cycles, which after six cycles, was followed by once every 2 weeks for persistent responders.[37] The applicant stated the ORR for ELREXFIO™ was 61 percent and the percentage of patients that had at least a complete response was 37.4 percent after a median follow-up of 17.6 months in patients with RRMM and no prior exposure to BCMA-directed therapy.[38] The applicant acknowledges the lack of head-to-head studies and submits indirect comparison analyses comparing ELREXFIO™ to belantamab, selinexor-dexamethasone, real-world physician's choice of treatment, real-world external control arms, and TECVAYLI® in patients with triple-class refractory multiple myeloma. The referenced indirect comparisons by Hlavacek et al. (2023)[39] and Costa et al. (2023)[40] [41] showed the ORR for ELREXFIO™ was significantly higher compared to belantamab, selinexor-dexamethasone, real-world physician's choice of treatment based on local clinical practice, and real-world external control arms. We note, however, that no similar comparative analyses were provided by the applicant to compare ELREXFIO™ to TALVEY™ ABECMA®, or CARVYKTI® . In the absence of direct comparative trials between ELREXFIO™ and TECVAYLI®, the applicant submitted the results of an unanchored matching-adjusted indirect comparison (MAIC) between the MagnetisMM–3 study, previously described, and the MajesTEC–1 study, assessing the relative efficacy of the two therapies in patients with relapsed or refractory MM naïve to prior BCMA-directed therapy (Isha Mol et al., 2023).[42] MajesTEC–1 was an open-label, phase 1–2 study where patients with RRMM and no prior exposure to BCMA-targeted therapy received a weekly subcutaneous injection of TECVAYLI® after two step-up doses.[43] As stated by the applicant, the results of the MAIC demonstrate ELREXFIO™ significantly improved ORR and PFS versus TECVAYLI®. We note, however, that the mechanism used in the MAIC to reweight MagnetisMM–3 patients to match the baseline characteristics of patients from MajesTEC–1 is unclear, as is the sensitivity analysis in which missing values of the adjusted baseline characteristics for ELREXFIO™ patients were imputed by a random sample of the observations in MagnetisMM–3 to potentially increase the effective sample size. In addition, while the ORR and PFS in the two analyses (base case adjusted and sensitivity analysis) were significantly improved with ELREXFIO™ over TECVAYLI®, we note that the confidence intervals were wide, reducing the certainty in these conclusions. The ORR odds ratio 95 percent confidence interval was 1.01 to 3.19 for the base case adjusted analysis and 1.04 to 3.14 for the sensitivity analysis. Furthermore, other outcomes

[37] Lesokhin AM, Tomasson MH, Arnulf B, et al. Elranatamab in relapsed or refractory multiple myeloma: Phase 2 MagnetisMM–3 trial results. Nat Med. 2023 Aug 15. Online ahead of print.

[38] Michael H. Tomasson, et al., Long-Term Efficacy and Safety of Elranatamab Monotherapy in the Phase 2 MagnetisMM–3 Trial in Relapsed or Refractory Multiple Myeloma. Oral presentation at: 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9–12.

[39] Hlavacek P, Mol I, Hu Y, et al. Indirect treatment comparison of elranatamab with belmaf, sel-dex, and real-world physician's choice of treatment in patients with triple-class exposed relapsed/refractory multiple myeloma. Presented at the European Hematology Association (EHA) Congress, 2023 June 8–11, Frankfurt, Germany.

[40] Costa LJ, LeBlanc TW, Tesch H, et al. An indirect comparison of elranatamab's (ELRA) objective response rate (ORR) from MagnetisMM–3 (MM–3) versus real-world external control arms in triple-class refractory (TCR) multiple myeloma (MM). Presented at the European Hematology Association (EHA) Congress, 2023 June 8–11, Frankfurt, Germany.

[41] Costa LJ, et al., An Indirect Comparison of Elranatamab's Progression-Free Survival and Overall Survival from MagnetisMM–3 Versus Real-World External Control Arms in Triple-Class Refractory Multiple Myeloma. Abstract presented at the 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9–12.

[42] Isha Mol, et al., A Matching-Adjusted Indirect Comparison of the Efficacy of Elranatamab and Teclistamab in Patients with Triple-Class Exposed/Refractory Multiple Myeloma. Oral presentation at: 65th American Society of Hematology (ASH) Annual Meeting; 2023 Dec. 9–12.

[43] Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in Relapsed or Refractory Multiple Myeloma. NEJM. 2022 Aug 11.

measured, such as the duration of response and overall survival, did not demonstrate significant improvement with ELREXFIO™. Additionally, we note that with regard to the claim that ELREXFIO™ significantly improves outcomes specifically in RRMM patients who have had prior BMCA-directed therapy, the applicant references the ELREXFIO™ prescribing information and additional MagnetisMM–3 Cohort B data showing an ORR of 33.3 percent in patients with prior BCMA-directed antibody drug conjugate (ADC) or CAR T-cell therapy. However, we note that TECVAYLI® and TALVEY™ may also be treatment options for BCMA-exposed patients and we would appreciate information on comparative efficacy between ELREXFIO™ and these treatment options in the prior BCMA-directed therapy population.

With respect to the claim that ELREXFIO™ offers fewer hospitalization days during the step-up dosing period than other bispecific antibodies approved for patients with RRMM, thus lowering barriers to patient access, the applicant references the prescribing information for ELREXFIO™, TECVAYLI®, and TALVEY™ to indicate that assuming patients are not sent home between step-up doses, based on the step-up dosing schedules, the patient would be hospitalized for 5 days with ELREXFIO™, 9 days with TECVAYLI®, and 9 to 12 days with TALVEY™. While the shorter step-up dosing may lead to a shorter hospitalization, the applicant assumes, but does not demonstrate that the shorter step-up dosing period and potentially shorter hospitalization would lower barriers to patient access. Additionally, we note that there are other variables besides duration of inpatient stay for the step-up dosing that may affect availability or access to therapies, such that a shorter step-up dosing duration may not necessarily result in better access to therapy. For instance, social, financial, age-related, prior therapy, and patient and provider dosing preferences may also affect access to therapy. Furthermore, while the shorter step-up dosing schedule should theoretically lead to a shorter hospitalization, we note that the risk and severity of adverse drug events and patient response could vary by drug, and that no clinical data was provided to support this claim.

We are inviting public comments on whether ELREXFIO™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ELREXFIO™.

e. FloPatch FP120

Flosonics Medical (R.A. 1929803 Ontario Corp.) submitted an application for new technology add-on payments for FloPatch FP120 for FY 2025. According to the applicant, FloPatch FP120 is a wireless, wearable, continuous wave (4 MHz) Doppler ultrasound device that adheres over peripheral vessels (that is, carotid & jugular) that assesses blood flow in the peripheral vessels, enabling rapid and repeatable dynamic assessments of both arterial and venous flow simultaneously. According to the applicant, the FloPatch FP120 cardiovascular blood flowmeter adheres to a patient's neck (or any other major vessel) and transmits Doppler-shifted ultrasonic waves from the transducer to the artery and vein at a fixed angle of insonation that are then reflected by moving blood cells back to the transducer. Per the applicant, the signal processing unit wirelessly outputs data to a secure iOS mobile medical application, which displays metrics from the Doppler signal, such as maximal velocity trace and corrected flow time, in a user-friendly interface. Per the applicant, FloPatch FP120 will optimize clinical workflow, is easy-to-use and hands-free, cloud-connected, and can be deployed in under one minute, providing instantaneous results.

Please refer to the online application posting for FloPatch FP120, available at *https://mearis.cms.gov/public/publications/ntap/NTP231017D56F4,* for additional detail describing the technology and the types of conditions that the technology might help diagnose and/or treat.

With respect to the newness criterion, according to the applicant, FloPatch FP120 received 510(k) clearance from FDA on May 3, 2023 for use for the noninvasive assessment of blood flow in the carotid artery. Per the applicant, in a more recent FDA 510(k) submission, the proposed indication is for use for the noninvasive assessment of blood flow in peripheral vasculature. However, based on the application submitted by the applicant, the new technology add-on payment application for FloPatch FP120 is not eligible for consideration for FY 2025 for the proposed indication (for use for the noninvasive assessment of blood flow in peripheral vasculature) because documentation of FDA acceptance or filing of the marketing authorization request, that indicates that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA, was not provided to CMS at the time of new technology add-on payment application submission. As such, the new technology add-on payment application for FloPatch FP120 is only eligible for consideration for FY 2025 for the narrower indication for use for the noninvasive assessment of blood flow in carotid artery.

We note that prior to the May 3, 2023 clearance, there were two FDA 510(k) clearances for the FloPatch FP120; one obtained in 2022 and one in 2020. The indications in the 2020, 2022, and 2023 clearances are identical, that is, for use for the noninvasive assessment of blood flow in the carotid artery.[44] In addition, the 2020 clearance was based on substantial equivalence to the FloPatch FP110 device,[45] which was an earlier version of FloPatch FP120 and was also FDA-cleared. According to the applicant, FloPatch FP120 was commercially available for this use as of January 1, 2023. However, as noted earlier, the provided FDA 510(k) clearance was dated May 3, 2023. Because the market availability date as indicated by the applicant preceded the 2023 clearance date, and because the 2020 and 2022 clearances had the same indication as the 2023 clearance, we question when the technology first became commercially available for use for the noninvasive assessment of blood flow in the carotid artery and request additional information on the market availability date for this indication. Per the applicant, one FloPatch FP120 device would be used per inpatient stay.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify FloPatch FP120. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for FloPatch FP120 beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for FloPatch FP120 under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered new for the purpose of new technology add-on payments.

[44] K223843, May 3, 2023; K222242, December 9, 2022; and K200337, March 24, 2020.

[45] K191388, June 21, 2019.

With respect to the substantial similarity criteria, the applicant asserted that FloPatch FP120 is not substantially similar to other currently available technologies because FloPatch FP120 offers real-time, non-invasive monitoring of hemodynamic changes of both the arterial and venous blood flow, improving fluid management decisions. Per the applicant, FloPatch FP120 surpasses current methods by providing continuous data, enhancing patient safety, and addressing unmet clinical needs for immediate, precise assessments, and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for FloPatch FP120, for the applicant's complete statements in support of its assertion that FloPatch FP120 is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	The applicant stated that FloPatch FP120 represents a significant advancement in hemodynamic monitoring technology, particularly in its application of Doppler ultrasound techniques. According to the applicant, while FloPatch FP120 employs traditional Doppler ultrasound technology for assessing blood flow, the FloPatch FP120 technology enhances this through its unique, patented sensor technology that generates a broad-beam, wide ultrasonic curtain to simultaneous insonate the arterial and venous vessels. The applicant noted that this allows for continuous, automated quantification of Doppler blood flow assessments on a beat-to-beat basis, providing a dynamic, real-time view of a patient's hemodynamic status, which is a significant departure from traditional methods. Furthermore, the applicant maintained that FloPatch FP120's unique capability to continuously assess both arterial and venous blood flow simultaneously offers a more holistic view of a patient's cardiovascular health and facilitates automated and continuous data collection.
Is the technology assigned to the same MS-DRG as existing technologies?	No	According to the applicant, FloPatch FP120 technology is so new that it has not been reviewed or assigned to a MS-DRG, nor is it comparable to existing technologies. In the context of MS-DRGs 870, 871, and 872, which pertain to septicemia or severe sepsis, the assessment of volume responsiveness is crucial. The applicant stated that since the device is new, it has not undergone sufficient review to be officially recognized as a standard or alternative treatment within the existing MS-DRGs.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	Per the applicant, existing technology does not provide clinicians with the information they need. The current standard for assessing a patient's volume status and fluid responsiveness involves either invasive cardiac output monitoring, which carries risks and discomfort, or clinical judgment without real-time objective data. The applicant argued that both methods have significant limitations, including the potential for delayed or inaccurate assessments, leading to suboptimal fluid management or worse fluid overload resulting in patient harm and excess costs due to longer and more complex lengths of stay. According to the applicant, in this context, FloPatch FP120 introduces a significant clinical advancement. Per the applicant, the FloPatch FP120 utilizes Doppler technology to continuously monitor simultaneous changes in blood flow of the arterial and venous systems, providing direct, real-time data regarding a patient's hemodynamic response to fluid administration. According to the applicant, this capability addresses a critical gap in patient management, particularly in dynamic assessments where understanding fluid responsiveness is crucial for decision-making and avoiding IV fluid overload for septic patients. The applicant stated that because the FP120 offers continuous, non-invasive assessments of changes in blood flow, use of the FP120 device not only reduces the risks associated with invasive procedures but also enhances the accuracy and frequency of assessments. Furthermore, the applicant asserted that the ability of the FP120 device to detect rapid physiological changes in blood flow enables healthcare professionals to make more informed decisions about fluid management, reducing the likelihood of both fluid overload and under-resuscitation. The applicant argued that the immediacy of data provided by the FloPatch FP120 allows for a more responsive form of care. The applicant maintained that by using the FloPatch FP120, clinicians can adjust fluid administration in real time, responding to the patient's current hemodynamic state rather than relying on intermittent monitoring or static indicators, which may not accurately reflect the patient's fluid responsiveness. The applicant maintained that the introduction of FloPatch FP120 represents a scientific and operational advancement in the management of patients requiring fluid resuscitation, particularly in settings characterized by a need for rapid, precise, and dynamic decision-making.

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We note the following concerns with regard to the newness criterion. With respect to the first substantial similarity criterion, whether FloPatch FP120 uses the same or similar mechanism of action for a therapeutic outcome when compared to existing technologies, we note we did not receive information from the applicant regarding predicate devices for FloPatch FP120 that were previously FDA-cleared in its discussion of existing technologies. As noted, there are three prior FDA 510(k) clearances for the FloPatch FP120, with the same indication for use for the noninvasive assessment of blood flow in the carotid artery.[46] In addition, the 2020 clearance was based on substantial equivalence to the FloPatch FP110 device,[47] which was an earlier version of FloPatch FP120 and was also FDA-cleared. We note that all of the FloPatch FP120 FDA-cleared devices, as well as the FP110 version have an identical method of attachment of the ultrasound probe to the human body, and the same intended use and indications for use. Accordingly, as the technology was already approved for use for this same indication outside of the 2- to 3-year newness period, it appears that it would no longer be considered new for purposes of new technology add-on payments.

In addition, we question whether a different placement method or the addition of a wearable functionality for the noninvasive assessment of blood flow would constitute a different mechanism of action, and also whether these differences may instead be relevant to the assessment of substantial clinical improvement, rather than of newness. For example, while the applicant described FloPatch FP120 as user-friendly, we question whether ease-of-use in itself represents a mechanism of action unique from existing technologies for a therapeutic outcome, as the primary underlying mechanism of action is still Doppler ultrasound technology.

With respect to the second substantial similarity criterion, that is, whether a product is assigned to the same or a different MS–DRG, although the applicant asserts that the device is new and has not undergone sufficient review to be recognized as a treatment within the existing MS–DRGs, we note that the applicant stated that FloPatch FP120 could be relevant to existing MS–DRGs that pertain to septicemia or severe sepsis for the assessment of volume responsiveness. We believe that, based on its indication, cases involving the use FloPatch FP120 would be assigned to the same MS–DRGs as those involving existing technologies used for invasive and non-invasive measurements of blood flow, such as for patients with septicemia or severe sepsis.

With respect to the third substantial similarity criterion, that is, whether the technology involves treatment of the same or similar type of disease or patient population when compared to an existing technology, the applicant maintained that existing technologies do not provide clinicians with the information they need, and while FloPatch LP120 serves a similar purpose as existing technology, its process has been optimized by providing a safer, more accurate, and instantaneous method of assessment. While this may be relevant to the assessment of substantial clinical improvement, it does not appear to be related to newness, and we remain unclear about how the patient population for which FloPatch FP120 is used differs from other patients for which existing non-invasive (for example, Doppler ultrasound devices) and invasive technologies are used for hemodynamic monitoring in a same or similar type of disease (such as septicemia or severe sepsis).

Accordingly, as it appears that the May 3, 2023 FDA 510(k) clearance and prior FDA 510(k) clearances for FloPatch FP120 may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if FloPatch FP120 as described in its 2023 FDA 510(k) clearance is substantially similar to prior versions as described in the 2022 and 2020 FDA 510(k) clearances, we believe the newness period for this technology would begin on March 24, 2020 with the earliest FDA 510(k) clearance date for FloPatch FP120 (K200337) and therefore, because the 3-year anniversary date of the technology's entry onto the U.S. market (March 24, 2023) occurred in FY 2023, the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2025.

We are inviting public comments on whether FloPatch FP120 is substantially similar to existing technologies and whether FloPatch FP120 meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for FloPatch FP120, the applicant searched the FY 2022 MedPAR for cases with ICD–10–CM diagnosis code category of E877 (Fluid overload, unspecified) and MS–DRG codes for septicemia or severe sepsis. Using the inclusion/exclusion criteria described in the following table, the applicant identified 690,320 cases mapping to septicemia or severe sepsis MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $93,703, which exceeded the average case-weighted threshold amount of $70,142. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that FloPatch FP120 meets the cost criterion.

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[46] K223843, May 3, 2023; K222242, December 9, 2022; and K200337, March 24, 2020.

[47] K191388, June 21, 2019.

FLOPATCH FP120 COST ANALYSIS	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	All codes within the category E877 (Fluid overload, unspecified)
List of MS-DRGs	870 (Septicemia or Severe Sepsis with MV >96 hours or Peripheral Extracorporeal Membrane Oxygenation (ECMO)) 871 (Septicemia or Severe Sepsis without MV >96 hours with MCC) 872 (Septicemia or Severe Sepsis without MV >96 hours without MCC)
Inclusion/exclusion criteria	The applicant identified cases by using all codes within the ICD-10-CM code category E877 with an accompanying MS-DRG of 870, 871, or 872.
Charges removed for prior technology	Per the applicant, the use of FloPatch FP120 would replace the use of an invasive cardiac output monitor such as Edwards Lifesciences Hemosphere, which uses an invasive arterial line and analyzes arterial pressure waveforms. The applicant removed estimated charges per patient for monitor and disposable sensor from the identified cases. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the corresponding national average cost-to-charge ratio from the FY 2024 IPPS/LTCH PPS final rule. Per the applicant, the cost of FloPatch FP120 device is determined based on the monthly software subscription plus the single patient use cost for the wearable FloPatch FP120 device. The applicant did not add indirect charges related to the new technology.

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We note the following concern regarding the cost criterion. Per the applicant, FloPatch FP120 is not indicated for use for a particular disease or diagnosis, but rather to assess changes in blood flow in response to a preload challenge and that it monitors hemodynamic change in response to a clinical intervention. We note that the applicant limited their coding determination and cost analysis to cases associated with a diagnosis of septicemia or severe sepsis with the identified MS–DRGs, 870, 871, and 872, as these are the cases for which FloPatch FP120 is best suited. However, the applicant stated that patients who are categorized under MS–DRGs other than 870, 871, and 872 can develop sepsis even though they are not initially admitted under a sepsis-related DRG, such as post-surgical patients or patients admitted for acute conditions like heart failure or chronic illnesses such as diabetes or renal disease. As these patients may also require vigilant monitoring for sepsis and fluid overload in a broader range of clinical scenarios, we are interested in additional information regarding whether such cases using the technology would map to other DRGs, and if those cases should also be included in the cost analysis.

We are inviting public comments on whether FloPatch FP120 meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that FloPatch FP120 overcomes barriers associated with traditional flow-directed therapies, which are often invasive and require specific expertise, by offering a non-invasive, user-friendly alternative. Per the applicant, the FloPatch FP120 makes precision fluid management more accessible, enabling early detection of preload unresponsiveness, thereby minimizing complications from over-resuscitation. The applicant asserted that FloPatch FP120 offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods; and that use of FloPatch FP120 significantly improves clinical outcomes relative to services or technologies previously available. The applicant provided five studies to support these claims. We also note that seven other articles submitted as supporting evidence should more appropriately be characterized as background articles because they do not directly assess the use of FloPatch FP120. Instead, those seven articles focus on the relationship between fluid responsiveness status during septic shock resuscitation.[48] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for FloPatch FP120 for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[48] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
Patient Accessibility to flow directed therapy	Kenny J-ÉS, Munding CE, Eibl JK, et al. (2021a) A novel, hands-free ultrasound patch for continuous monitoring of quantitative Doppler in the carotid artery. *Scientific Reports* 11(1):1-11. Kenny J-ÉS, Gibbs SO, Johnston D, et al. (2023a) The time cost of physiologically ineffective intravenous fluids in the emergency department: an observational pilot study employing wearable Doppler ultrasound. *Journal of Intensive Care* 11:7 https://doi.org/10.1186/s40560-023-00655-6.
Substantial Clinical Improvement Assertion #2: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods	
Applicant statements in support	**Supporting evidence provided by the applicant**
Diagnosing preload unresponsiveness early in care is important because it reduces complications	Kenny J-ÉS, Munding CE, Eibl JK, et al. (2021a) A novel, hands-free ultrasound patch for continuous monitoring of quantitative Doppler in the carotid artery. *Scientific Reports* 11(1):1-11. Kenny J-ÉS, Barjaktarevic I, Mackenzie DC, et al. (2021b) Inferring the Frank–Starling Curve From Simultaneous Venous and Arterial Doppler: Measurements From a Wireless, Wearable Ultrasound Patch [Hypothesis and Theory]. *Frontiers in Medical Technology* 2021-May-14 3(16). https://doi.org10.3389/fmedt.2021.676995 Kenny JS, Barjaktarevic I, Mackenzie DC, et al. (2021c) Carotid Doppler ultrasonography correlates with stroke volume in a human model of mypovolaemia and resuscitation: analysis of 48 570 cycles. *British Journal of Anesthesia* 127(2):E62-E63. Kenny J-ÉS, Gibbs SO, Johnston D, et al. (2023a) The time cost of physiologically ineffective intravenous fluids in the emergency department: an observational pilot study employing wearable Doppler ultrasound. *Journal of Intensive Care* 11:7 https://doi.org/10.1186/s40560-023-00655-6. Kenny JS, Gibbs SO, Eibl JK, et al. (2023b) Simultaneous venous-arterial Doppler during preload augmentation: illustrating the Doppler Starling curve. *Ultrasound J* Jul 28. 15(1):32. https://doi.org10.1186/s13089-023-00330-9
Substantial Clinical Improvement Assertion #3: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Current services for sepsis patients are providing IV fluids without flow guidance	Kenny J-ÉS, Munding CE, Eibl JK, et al. (2021a) A novel, hands-free ultrasound patch for continuous monitoring of quantitative Doppler in the carotid artery. *Scientific Reports* 11(1):1-11. Kenny J-ÉS, Gibbs SO, Johnston D, et al. (2023a) The time cost of physiologically ineffective intravenous fluids in the emergency department: an observational pilot study employing wearable Doppler ultrasound. *Journal of Intensive Care* 11:7 https://doi.org/10.1186/s40560-023-00655-6 Kenny JS, Gibbs SO, Eibl JK, et al. (2023b) Simultaneous venous-arterial Doppler during preload augmentation: illustrating the Doppler Starling curve. *Ultrasound J* Jul 28. 15(1):32. https://doi.org10.1186/s13089-023-00330-9

We note the following concerns regarding whether FloPatch FP120 meets the substantial clinical improvement criterion.

In support of its assertion that FloPatch FP120 offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant stated that FloPatch FP120 improves patient accessibility to flow-directed therapy. The applicant referred to the Kenny et al. (2021a)[49] study that focused on a novel, hands-free CW Doppler patch developed for easily and continuously monitoring changes in blood flow velocities in the common carotid artery. The study included in vitro experiments conducted using moving string and blood-mimicking flow phantoms; a small usability study with 22 participants, and an in vivo proof-of-concept study with one healthy volunteer and one congestive heart failure patient. While the study found that the CW Doppler patch demonstrated accuracy in identifying changes in target velocity in string and flow phantom experiments, that it was easy to use, and that the Doppler patch could continuously record and track instantaneous changes in carotid velocity time integral (VTI) during a passive leg raise, we question if the evidence demonstrates that the FloPatch FP120 substantially improves patient accessibility to flow directed therapy relative to existing technologies. We would be interested in evidence comparing the use of FloPatch FP120 and existing technologies to demonstrate improvements in patient accessibility. In addition, we note that the study had small sample sizes, which may raise concerns about the reliability of the findings.

To support its claim that FloPatch FP120 improves patient accessibility to flow-directed therapy, the applicant also included findings from the Kenny et al. (2023a)[50] study about the time cost of physiologically ineffective intravenous fluid in the emergency department (ED). Per the applicant, this study sought to

[49] Kenny J-ÉS, Munding CE, Eibl JK, et al. (2021a) A novel, hands-free ultrasound patch for continuous monitoring of quantitative Doppler in the carotid artery. *Scientific Reports* 11(1):1–11.

[50] Kenny J-ÉS, Gibbs SO, Johnston D, et al. (2023a) The time cost of physiologically ineffective intravenous fluids in the emergency department: an observational pilot study employing wearable Doppler ultrasound. *Journal of Intensive Care* 11:7 *https://doi.org/10.1186/s40560-023-00655-6.*

quantify the burden of fluid unresponsiveness early in ED care and calculate the time spent providing physiologically ineffective IV fluid using FloPatch FP120. It was a prospective study design, using a convenience sample of 51 adult patients presenting to a single community ED requiring IV fluid expansion for any indication, and identified 86 preload challenges, and 19,667 carotid Doppler beats. The study authors concluded that a clinically significant fraction of fluid unresponsive or refractory patients was observed early in their ED care, and a considerable amount of time was spent providing physiologically ineffective IV fluid, and that these findings may indicate an area in ED care where using wearable Doppler ultrasound technology, like FloPatch FP120, would improve clinical efficiency. We question whether these findings can be replicated in studies with a larger sample. We also question if a study using a patient sample representative of those potentially appropriate for FloPatch FP120 would yield similar results as one using a convenience sample. In addition, we are interested in whether a multi-center trial would generate the same result as a single-site study, where site-specific attributes could potentially confound study results, reducing the reliability of the findings.

The applicant also asserted that FloPatch FP120 is able to diagnose sepsis in a population where sepsis is currently undetectable, or to diagnose it earlier than currently available technologies. The applicant claimed that diagnosing preload unresponsiveness early in care is important because doing so reduces complications. However, although the applicant provided studies demonstrating that FloPatch FP120 can diagnose sepsis, these studies do not appear to demonstrate that the use of the technology to make a diagnosis affected the management of the patients, as required under § 412.87(b)(1)(ii)(B). For example, in the Kenny et al. (2023a) [51] study on time cost of physiologically ineffective intravenous fluids in the ED, as discussed earlier, there was no evidence linking the use of FloPatch FP120 to changes in the management of patients such as initiating or discontinuing IV fluid expansion.

To further support its claim that diagnosing preload unresponsiveness early in care is important because doing so reduces complications, the applicant also used the Kenny et al. (2021c) [52] study about correlation between carotid Doppler ultrasonography and stroke volume. The study found that compared with existing handheld Doppler devices, FloPatch FP120 was able to capture and analyze a large number of cardiac cycles, account for inherent SV variation over many cardiorespiratory cycles, and eliminate the effects of human errors. The applicant hypothesized that when measured over many cardiac cycles, monitoring SV change using FloPatch FP120 might support diagnosis and management of evolving hypovolemia. While this study and those discussed earlier demonstrated that FloPatch FP120 provided noninvasive assessment of blood flow to determine SV changes, similar to our previous concern, we remain interested in evidence showing how use of the technology to make a diagnosis affects the management of patients, such as the use of FloPatch FP120 to initiate or discontinue IV fluid expansion in response to the observed SV changes.

The applicant also referred to the findings of the Kenny et al. (2023b) [53] study on simultaneous venous-arterial Doppler during preload augmentation to support its claim that diagnosing preload unresponsiveness early in care is important because it reduces complications. In that study, the researchers concluded that FloPatch FP120 (referenced as the wearable Doppler biosensor) can help identify patients with dynamic fluid intolerance, potentially guiding IV fluid management and preventing downstream complications and costs. We are concerned that the small clinical sample size and presence of potential confounders could call into question the reliability and validity of the findings. In addition, we note that this study does not appear to demonstrate that use of FloPatch FP120 to assess preload responsiveness affected the management of the patients, as the study states that the treating clinician was blinded to the results of the wearable ultrasound and that the choice for preload augmentation was at the discretion of the treating clinician.

To support the assertion that FloPatch FP120 significantly improves clinical outcomes relative to services or technologies previously available, the applicant claimed that current services for sepsis patients are providing IV fluids without flow guidance, and referred to three Kenny studies (2021a, 2023a, and 2023b), discussed earlier. As discussed, we are interested in additional evidence that assesses the impact of FloPatch FP120 compared to existing technologies that can be used to provide flow guidance on clinical outcomes.

We are inviting public comments on whether FloPatch FP120 meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for FloPatch FP120.

f. HEPZATO™ KIT (Melphalan for Injection/Hepatic Delivery System)

Delcath System submitted an application for new technology add-on payments for HEPZATO™ KIT for FY 2025. According to the applicant, HEPZATO™ KIT is a drug/device combination product consisting of melphalan and the Hepatic Delivery System (HDS), indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases. Per the applicant, the HDS is used to perform percutaneous hepatic perfusion (PHP), an intensive local hepatic chemotherapy procedure, in which the alkylating agent melphalan hydrochloride is delivered intra-arterially to the liver with simultaneous extracorporeal filtration of hepatic venous blood return (hemofiltration).

Please refer to the online application posting for HEPZATO™ KIT, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310160RLLX,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, HEPZATO™ KIT was granted approval as a New Drug Application (NDA) from FDA on August 14, 2023, for use as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50 percent of the liver and no extrahepatic disease or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. According to the

[51] Kenny J-ÉS, Gibbs SO, Johnston D, et al. (2023a) The time cost of physiologically ineffective intravenous fluids in the emergency department: an observational pilot study employing wearable Doppler ultrasound. *Journal of Intensive Care* 11:7 *https://doi.org/10.1186/s40560-023-00655-6.*

[52] Kenny JS, Barjaktarevic I, Mackenzie DC, et al. Carotid Doppler ultrasonography correlates with stroke volume in a human model of mypovolaemia and resuscitation: analysis of 48 570 cycles. *British Journal of Anesthesia* 2021c. 127(2):E62–E63.

[53] Kenny JS, Gibbs SO, Eibl JK, et al. (2023b) Simultaneous venous-arterial Doppler during preload augmentation: illustrating the Doppler Starling curve. *Ultrasound J* Jul 28;15(1):32. *https://doi.org10.1186/s13089-023-00330-9.*

applicant, the technology became available for sale on January 8, 2024, because manufacturing did not commence until after FDA approval was granted. Melphalan hydrochloride, a component of the HEPZATO™ KIT, is administered by intra-arterial infusion into the hepatic artery at a dose of 3 mg/kg of body weight with a maximum dose of 220 mg during a single HEPZATO treatment. The drug is infused over 30 minutes, followed by a 30-minute washout period. According to the applicant, treatments should be administered every 6 to 8 weeks, but can be delayed until recovery from toxicities, and as per clinical judgement.

The applicant stated that, effective October 1, 2023, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of HEPZATO™ KIT: XW053T9 (Introduction of melphalan hydrochloride antineoplastic into peripheral artery, percutaneous approach, new technology group 9). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for HEPZATO™ KIT under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM and ICD–10–PCS codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that HEPZATO™ KIT is not substantially similar to other currently available technologies because it offers the first liver-directed treatment option to patients with liver-dominant metastatic ocular melanoma (mOM) who may be poor candidates for liver resection and/or who may have difficulty tolerating systemic chemotherapy. According to the applicant, HEPZATO™ KIT uses a unique PHP procedure to isolate liver circulation and deliver a high concentration of melphalan to liver tumors via infusion followed by filtration of the hepatic venous flow to remove melphalan out of the blood with extracorporeal filters, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for HEPZATO™ KIT for the applicant's complete statements in support of its assertion that HEPZATO™ KIT is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	The HEPZATO™ KIT uses a liver-directed PHP procedure to isolate liver circulation and deliver a high concentration of the chemotherapeutic, melphalan to liver tumors via infusion followed by filtration of the hepatic venous flow to remove melphalan out of the blood with extracorporeal filters before returning the blood to the patient's systemic circulation. Regional treatment of the liver is possible by utilizing its unique dual blood supply. Whereas normal liver cells receive their blood primarily from the portal vein, liver tumors are supplied almost exclusively (up to 95%) by the hepatic artery. This allows for isolation of the hepatic arterial inflow and venous outflow, where a 30-minute infusion of melphalan can be delivered directly to unresectable liver metastases while sparing healthy liver tissue by limiting systemic exposure. Chemosaturation with PHP relies on placing a unique double-balloon catheter percutaneously into the inferior vena cava to isolate the hepatic venous blood. High doses of melphalan can then be infused directly into the hepatic artery. A fenestrated section in the double-balloon catheter allows the isolated hepatic blood to be filtered extra-corporeally before being returned to systemic circulation. There are currently no other FDA approved liver-directed therapies for patients with liver-dominant mOM.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Use of the HEPZATO™ KIT will likely be assigned to the following DRGs where other chemotherapies administered during inpatient stays would also be assigned: 826 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC); 827 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with CC); 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures without CC/MCC); 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with other Procedures with CC/MCC); 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with other Procedures without CC/MCC); 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC); 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC); or 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis without CC/MCC).
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	The HEPZATO™ KIT treats patients with liver-dominant mOM who may be poor candidates for liver resection and/or who may have difficulty tolerating systemic chemotherapy. This patient population does not have FDA approved treatment options available. Where possible, metastatic ocular melanoma is treated through surgical resection, although this is not always feasible, and clinicians may employ a range of liver-directed and systemic therapies. Liver-directed therapies can be utilized to deliver targeted treatment to the liver, including regional isolation perfusion of the liver, embolization techniques, and ablative procedures. Systemic therapies use drugs to deliver treatment throughout the body via blood circulation so as to have an effect on all cells throughout the body, including cancerous cells. However, there are currently no systemic therapies that have reliably demonstrated improvement in overall survival outcomes in patients with mOM in the liver.

BILLING CODE 4120–01–C

We are inviting public comments on whether HEPZATO™ KIT is substantially similar to existing technologies and whether HEPZATO™ KIT meets the newness criterion. We are also inviting public comments on drug-device combination technology considerations for new technology add-on payments. Specifically, we seek comment on whether reformatting the delivery mechanism for a drug would represent a new mechanism of action for drug-device combination technologies, and on factors that should be considered when considering new technology add-on payments for technologies that may use a drug or device component that is no longer new in combination with a new drug or device component.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR file using a combination of ICD–10–CM and/or PCS codes to identify potential cases representing patients who may be eligible for HEPZATO™ KIT. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for HEPZATO™ KIT because it is indicated for a rare condition, hepatic-dominant mOM, which does not have a unique ICD–10–CM diagnosis code to identify potential cases with the specific diagnosis of interest, nor a unique ICD–10–PCS procedure code that would identify patients receiving this specific procedure. The applicant believed the cases identified in the analysis are the closest proxies to the cases potentially eligible for the use of HEPZATO™ KIT. Each analysis followed the order of operations described in the table later in this section.

For the first analysis, the applicant searched for cases with ICD–10–PCS code 3E05305 (Introduction of other antineoplastic into peripheral artery, percutaneous approach) for the PHP procedure, and ICD–10–CM code Z51.11 (Encounter for antineoplastic chemotherapy) as the primary diagnosis for the administration of chemotherapy during an inpatient stay. In addition, the applicant narrowed the analysis to cases with liver-dominant mOM using at least one secondary liver metastases diagnosis plus at least one ocular melanoma diagnosis. Please see the online posting for HEPZATO™ KIT for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 11 claims mapping to one MS–DRG: 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC). The applicant calculated a final inflated average case-weighted standardized charge per case of $1,068,530, which exceeded the average case-weighted threshold amount of $104,848.

For the second analysis, the applicant searched for the following combination of ICD–10–CM diagnosis codes: Z51.11 (Encounter for antineoplastic chemotherapy) as the primary diagnosis code, in combination with at least one of the following secondary liver metastases codes: C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct), or C22.9 (Malignant neoplasm of liver, not specified as primary or secondary). The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 1,134 claims mapping to nine MS–DRGs, with 94 percent of identified cases mapping to three MS–DRGs: 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC), as well as 846 and 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC, and with CC, respectively). The applicant calculated a final inflated average case-weighted standardized charge per case of $1,066,207, which exceeded the average case-weighted threshold amount of $81,652.

For the third analysis, the applicant searched for cases where the ICD–10–CM code Z51.11 (Encounter for antineoplastic chemotherapy) is the primary diagnosis or the ICD–10 PCS code 3E05305 (Introduction of other antineoplastic into peripheral artery, percutaneous approach) is reported. In addition, the case also needed to include at least one of the following secondary liver metastases codes: C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) or C22.9 (Malignant neoplasm of liver, not specified as primary or secondary). The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 1,277 claims mapping to 12 MS–DRGs with 92 percent of identified cases mapping to three MS–DRGs: 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC); as well as 846 and 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC, and with CC, respectively). The applicant calculated a final inflated average case-weighted standardized charge per case of $1,067,772, which exceeded the average case-weighted threshold amount of $80,245.

For the fourth analysis, the applicant searched for cases reporting the following combination of ICD–10–CM diagnosis codes: C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) or C22.9 (Malignant neoplasm of liver), in combination with at least one ocular melanoma ICD–10–CM code. Please see the online posting for HEPZATO™ KIT for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 1,059 claims mapping to 91 MS–DRGs with none exceeding 4.91 percent. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,062,553, which exceeded the average case-weighted threshold amount of $66,104.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that HEPZATO™ KIT meets the cost criterion.

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HEPZATO™ KIT COST ANALYSIS[54]	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	Analysis 1 and 4: For the list of ICD-10-CM codes, see the online posting for HEPZATO™ KIT. Analysis 2 and 3: Z51.11 (Encounter for antineoplastic chemotherapy) C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) C22.9 (Malignant neoplasm of liver, not specified as primary or secondary)
List of ICD-10-PCS codes	Analysis 1 and 3: 3E05305 (Introduction of other antineoplastic into peripheral artery, percutaneous approach) Analysis 2 and 4: Not applicable
List of MS-DRGs	Analysis 1: 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) Analysis 2: 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis except Face, Mouth, and Neck without Major O.R. Procedures) 016 (Autologous Bone Marrow Transplant with CC/MCC) 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) 826 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC) 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC) 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent) 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC) Analysis 3: 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis except Face, Mouth, and Neck without Major O.R. Procedures) 016 (Autologous Bone Marrow Transplant with CC/MCC) 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) 826 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC) 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures without CC/MCC) 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC)

[54] Lists referenced here may be found in the cost criterion codes and MS-DRGs attachment included in the online posting for the technology.

	838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent) 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC) 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC) 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis without CC/MCC) Analysis 4: For the list of MS-DRGs, see the online posting for HEPZATO™ KIT.
Inclusion/ exclusion criteria	Analysis 1: The applicant selected claims based on the ICD-10-PCS code listed previously, plus ICD-10-CM code Z51.11 (Encounter for antineoplastic chemotherapy) as the primary diagnosis, and at least one secondary liver metastases diagnosis plus at least one ocular melanoma diagnosis. Please see the online posting for HEPZATO™ KIT for the complete list of ICD-10-CM codes provided. The applicant believes this analysis represents what would likely be used to report the HEPZATO™ KIT procedure if it were billed today. Analysis 2: The applicant selected claims based on the ICD-10-CM diagnosis code Z51.11 (Encounter for antineoplastic chemotherapy) as the primary diagnosis code, in combination with at least one of the following secondary liver metastases ICD-10-CM codes: C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) or C22.9 (Malignant neoplasm of liver, not specified as primary or secondary). The applicant provided this analysis to focus on the melphalan hydrochloride chemotherapy component of the HEPZATO™ KIT. Analysis 3: The applicant selected claims based on the ICD-10-CM diagnosis code Z51.11 (Encounter for antineoplastic chemotherapy) as the primary diagnosis and/or reporting of the ICD-10-PCS code listed previously. In addition, cases must include at least one of the following secondary liver metastases codes: C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) or C22.9 (Malignant neoplasm of liver, not specified as primary or secondary). The applicant included this analysis to focus on the combination of the melphalan hydrochloride chemotherapy component of the HEPZATO™ KIT and the PHP procedure. Analysis 4: The applicant selected claims based on reporting of at least one secondary liver metastasis diagnosis [either C78.7 (Secondary malignant neoplasm of liver and intrahepatic bile duct) or C22.9 (Malignant neoplasm of liver)], in combination with at least one ocular melanoma ICD-10-CM code. Please see the online posting for HEPZATO™ KIT for the complete list of ICD-10-CM codes provided by the applicant. The applicant provided this analysis to demonstrate how the costs/charges of HEPZATO KIT compared to existing treatment options for liver-dominant mOM, so the focus was inclusion of diagnosis codes for the target patient population.
Charges removed for prior technology	The applicant stated HEPZATO™ KIT is expected to replace other drugs patients currently receive for the treatment of metastatic ocular melanoma. As such, averages of charges (per MS-DRG) associated with the drug cost center in the FY 2022 MedPAR file were removed. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.18 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether HEPZATO™ KIT meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that HEPZATO™ KIT represents a substantial clinical improvement over existing technologies because it offers a minimally invasive, targeted, effective, and safe treatment option to patients with liver-dominant mOM who may be poor candidates for liver resection or who may have difficulty tolerating systemic chemotherapy which results in a substantial clinical improvement in response and survival rates over best available care and quality of life compared to pre-treatment. The applicant provided 11 studies to support these claims, as well as one background article about use of chemosaturation with PHP (CS–PHP) as a palliative treatment option for patients with unresectable cholangiocarcinoma.[55] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for HEPZATO™

[55] Background articles are not included in the following table but can be accessed via the online posting for the technology.

KIT for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
Offers a treatment option for a patient population unresponsive or ineligible for, currently available treatments	None Provided.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Increased response rate over best available care	Meijer TS, Geus-Oei LF, Martini CH, et al. Embolization of variant hepatic arteries in patients undergoing percutaneous hepatic perfusion for unresectable liver metastases from ocular melanoma. Diagn Interv Radiol. Nov 2019;25(6):451-458. Meijer TS, Burgmans MC, de Leede EM, et al. Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase II Study. Ann Surg Oncol. Feb 2021;28(2):1130-1141. Delcath ASCO 2022 FOCUS Trial Poster. Dewald CLA, Hinrichs JB, Becker LS, et al. Chemosaturation with Percutaneous Hepatic Perfusion: Outcome and Safety in Patients with Metastasized Uveal Melanoma. Rofo. Aug 2021;193(8):928-936. Artzner C, Mossakowski O, Hefferman G, et al. Chemosaturation with percutaneous hepatic perfusion of melphalan for liver-dominant metastatic uveal melanoma: a single center experience. Cancer Imaging. May 30, 2019;19(1):31. Vogl TJ, Koch SA, Lotz G, et al. Percutaneous Isolated Hepatic Perfusion as a Treatment for Isolated Hepatic Metastases of Uveal Melanoma: Patient Outcome and Safety in a Multi-centre Study. Cardiovasc Intervent Radiol. Jun 2017;40(6):864-872. Tong TML, Samim M, Kapiteijn E, et al. Predictive parameters in patients undergoing percutaneous hepatic perfusion with melphalan for unresectable liver metastases from uveal melanoma: a retrospective pooled analysis. Cardiovasc Intervent Radiol. 2022;45(9):1304–1313. doi: 10.1007/s00270-022-03225-9. Karydis I, Gangi A, Wheater MJ, et al. Percutaneous hepatic perfusion with melphalan in uveal melanoma: A safe and effective treatment modality in an orphan disease. J Surg Oncol. May 2018;117(6):1170-1178.

	Bruning R, Tiede M, Schneider M, et al. Unresectable Hepatic Metastasis of Uveal Melanoma: Hepatic Chemosaturation with High-Dose Melphalan-Long-Term Overall Survival Negatively Correlates with Tumor Burden. Radiol Res Pract. 2020. The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Improves survival over other treatment options	Hughes MS, Zager J, Faries M, et al. Results of a Randomized Controlled Multicenter Phase III Trial of Percutaneous Hepatic Perfusion Compared with Best Available Care for Patients with Melanoma Liver Metastases. Ann Surg Oncol. Apr 2016;23(4):1309-19. Meijer TS, Burgmans MC, de Leede EM, et al. Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase II Study. Ann Surg Oncol. Feb 2021;28(2):1130-1141. Dewald CLA, Hinrichs JB, Becker LS, et al. Chemosaturation with Percutaneous Hepatic Perfusion: Outcome and Safety in Patients with Metastasized Uveal Melanoma. Rofo. Aug 2021;193(8):928-936. Artzner C, Mossakowski O, Hefferman G, et al. Chemosaturation with percutaneous hepatic perfusion of melphalan for liver-dominant metastatic uveal melanoma: a single center experience. Cancer Imaging. May 30, 2019;19(1):31. Vogl TJ, Koch SA, Lotz G, et al. Percutaneous Isolated Hepatic Perfusion as a Treatment for Isolated Hepatic Metastases of Uveal Melanoma: Patient Outcome and Safety in a Multi-centre Study. Cardiovasc Intervent Radiol. Jun 2017;40(6):864-872. Tong TML, Samim M, Kapiteijn E, et al. Predictive parameters in patients undergoing percutaneous hepatic perfusion with melphalan for unresectable liver metastases from uveal melanoma: a retrospective pooled analysis. Cardiovasc Intervent Radiol. 2022;45(9):1304–1313. doi: 10.1007/s00270-022-03225-9. Karydis I, Gangi A, Wheater MJ, et al. Percutaneous hepatic perfusion with melphalan in uveal melanoma: A safe and effective treatment modality in an orphan disease. J Surg Oncol. May 2018;117(6):1170-1178. Bruning R, Tiede M, Schneider M, et al. Unresectable Hepatic Metastasis of Uveal Melanoma: Hepatic Chemosaturation with High-Dose Melphalan-Long-Term Overall Survival Negatively Correlates with Tumor Burden. Radiol Res Pract. 2020. Delcath ASCO 2022 FOCUS Trial Poster. FOCUS Trial Ongoing (NCT02678572). The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Improves quality of life over pre-treatment	Vogl TJ, Koch SA, Lotz G, et al. Percutaneous Isolated Hepatic Perfusion as a Treatment for Isolated Hepatic Metastases of Uveal Melanoma: Patient Outcome and Safety in a Multi-centre Study. Cardiovasc Intervent Radiol. Jun 2017;40(6):864-872.

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After review of the information provided by the applicant, we have the following concerns regarding whether HEPZATO™ KIT meets the substantial clinical improvement criterion. With respect to the applicant's assertion that HEPZATO™ KIT offers a treatment option for a patient population unresponsive or ineligible for currently available treatments, while the applicant stated that HEPZATO™ KIT offers an additional treatment option to patients with liver-dominant mOM who may be poor candidates for liver resection or who may have difficulty tolerating systemic chemotherapy, it did not provide evidence in support of this assertion. We would be interested in information regarding whether there are potential Medicare patient populations that may have difficulty tolerating (or be unresponsive to) KIMMTRAK® or other currently available treatments, but would be a good candidate for HEPZATO™ KIT.

Regarding the claim that HEPZATO™ KIT improves survival over other treatment options, the applicant provided seven peer-reviewed cohort studies, summary material from an unpublished study, and one randomized controlled clinical study to support the claim.

The seven peer reviewed cohort studies [56] [57] [58] [59] [60] [61] [62] provide a range of results of overall survival as reported for patients treated with the HEPZATO™ KIT (median overall survival after first Chemosaturation with Percutaneous Hepatic Perfusion [CS–PHP] ranged from 9.6 months to 27.4 months depending on the study, and median one-year overall survival rate raged from 44 percent to 77 percent depending on study). A few of the seven peer reviewed cohort studies (Karydis et al. (2018), Tong et al. (2022); Meier et al. (2021)) reported statistically significant improvement in overall survival (OS) when compared to non-responders or stable disease groups. Only one of the seven studies, Dewald et al. (2021), compared results to alternative treatments, but statistical significance was not achieved (P = 0.97) with CS–PHP resulting in a median OS of 24.1 months compared with 23.6 months for patients receiving other therapies. We believe that additional evidence supporting that HEPZATO™ KIT offers a significant difference in OS rates compared to currently available treatments would be helpful in our evaluation of the applicant's assertion. We note that several of the studies provided as evidence include small, non-randomized studies without the use of comparators or controls, which may affect the ability to draw meaningful conclusions about treatment outcomes from the results of the studies. We also note that a majority of the studies provided (Bruning et al. (2020); Vogl et al. (2017); Dewald et al. (2021); Meijer et al. (2021); and Artzner et al. (2019)) were conducted outside the United States. We question if there may be differences in treatment guidelines between these countries that may have affected clinical outcomes.

The applicant also submitted summary presentation material evidence to support this claim in the form of a poster and slides for the FOCUS study,[63] in which 144 patients were enrolled, with 91 patients receiving percutaneous hepatic perfusion (PHP) treatment and 32 patients receiving best available care (BAC). According to the applicant, preliminary results from the phase III FOCUS Trial show that progression free survival (PFS) was 9.03 months among PHP patients and just over 3 months among best available care (BAC) patients. OS among treated PHP patients was 19.25 months and among treated BAC patients was 14.49 months. However, this study has yet to be published and is not yet available for analysis and peer review. At this point, we are unable to verify the methods, results, and conclusions of this study as the applicant only provided evidence in the form of a poster and presentation. For example, one citation provided by the applicant in the form of a non-peer-reviewed conference presentation details preliminary results from the FOCUS Phase III Trial. We would be interested in the statistical analysis (including p value and CI data) surrounding the OS rates. In addition, the poster notes that due to slow enrollment and patient reluctance to receive BAC treatment, the trial design was amended to a single arm design with all eligible patients receiving PHP after discussion with FDA. We would be interested in detail about these specific eligibility requirements, as well as how the potential for confounding variables resulting from any differences in the resulting populations were identified and mitigated.

In the published randomized clinical trial [64] (RCT) provided by the applicant, the median hepatic progression free survival (hPFS), the primary endpoint of the trial, was 7.0 months for patients using HEPZATO™ KIT compared to 1.6 months for patients receiving BAC. However, the median overall survival (OS) with the treatment of HEPZATO™ KIT was 10.6 months (95 percent CI 6.9–13.6 months) compared to 10.0 months (95 percent CI 6.0–13.1 months) for the group of patients who received BAC. The study notes that median OS was not significantly different (PHP-Mel 10.6 months vs. BAC 10.0 months), but OS was 13.1 months (95 percent CI 10.0–20.3 months) in BAC patients who crossed over and received treatment with PHP-Mel (n = 28, 57.1 percent). In the study discussion of OS, Hughes, et al. concluded that the 57 percent of patients who were allowed to crossover confounded the ability to analyze any survival advantage associated with PHP Mel. We would be interested in additional evidence in our evaluation of the applicant's assertion that HEPZATO™ KIT substantially improves survival over other treatment options.

Regarding the claim that HEPZATO™ KIT increases response rate over BAC, we note that across the retrospective studies, response rates ranged from an overall response rate of 42.3 percent [Dewald et al (2021)] to a partial response of 89 percent [Vogl et al. (2017)] depending on the study. However, as the applicant cited to many of the same retroactive studies that it referenced in support of the claim of improved survival [Bruning et al. (2020); Vogl et al. (2017); Dewald et al. (2021); Meijer et al. (2021); Artzner et al. (2019); Tong et al. (2022); Karydis et al. (2018)], we have the same questions as discussed previously regarding the ability to draw meaningful conclusions from the results of these studies in evaluation of this claim.

Regarding the unpublished FOCUS study (Delcath ASCO 2022 FOCUS Trial Poster),[65] previously described, the applicant stated that in the preliminary results from the FOCUS Trial, the overall response rate (ORR) among PHP patients was 36.3 percent, nearly three

[56] Bruning R, Tiede M, Schneider M, et al. Unresectable Hepatic Metastasis of Uveal Melanoma: Hepatic Chemosaturation with High-Dose Melphalan-Long-Term Overall Survival Negatively Correlates with Tumor Burden. Radiol Res Pract. 2020.

[57] Vogl TJ, Koch SA, Lotz G, et al. Percutaneous Isolated Hepatic Perfusion as a Treatment for Isolated Hepatic Metastases of Uveal Melanoma: Patient Outcome and Safety in a Multi-centre Study. Cardiovasc Intervent Radiol. Jun 2017;40(6):864–872.

[58] Dewald CLA, Hinrichs JB, Becker LS, et al. Chemosaturation with Percutaneous Hepatic Perfusion: Outcome and Safety in Patients with Metastasized Uveal Melanoma. Rofo. Aug 2021;193(8):928–936.

[59] Meijer TS, Burgmans MC, de Leede EM, et al. Percutaneous Hepatic Perfusion with Melphalan in Patients with Unresectable Ocular Melanoma Metastases Confined to the Liver: A Prospective Phase II Study. Ann Surg Oncol. Feb 2021;28(2):1130–1141.

[60] Karydis I, Gangi A, Wheater MJ, et al. Percutaneous hepatic perfusion with melphalan in uveal melanoma: A safe and effective treatment modality in an orphan disease. J Surg Oncol. May 2018;117(6):1170–1178.

[61] Artzner C, Mossakowski O, Hefferman G, et al. Chemosaturation with percutaneous hepatic perfusion of melphalan for liver-dominant metastatic uveal melanoma: a single center experience. Cancer Imaging. Mayphip 30 2019;19(1):31.

[62] Tong TML, Samim M, Kapiteijn E, et al. Predictive parameters in patients undergoing percutaneous hepatic perfusion with melphalan for unresectable liver metastases from uveal melanoma: a retrospective pooled analysis. Cardiovasc Intervent Radiol. 2022;45(9):1304–1313.

[63] Delcath ASCO 2022 FOCUS Trial Poster; FOCUS Trial Ongoing (See online posting for Hepzato™ Kit).

[64] Hughes MS, Zager J, Faries M, et al. Results of a Randomized Controlled Multicenter Phase III Trial of Percutaneous Hepatic Perfusion Compared with Best Available Care for Patients with Melanoma Liver Metastases. Ann Surg Oncol. Apr 2016;23(4):1309–19.

[65] Delcath ASCO 2022 FOCUS Trial Poster; FOCUS Trial Ongoing (See online posting for Hepzato™ Kit).

times better that the 12.5 percent ORR among BAC patients. However, as previously noted, we would be interested in details about the eligibility requirements, and how the potential for confounding variables resulting from any differences in the resulting populations were identified and mitigated.

Lastly, with regard to the assertion that HEPZATO™ KIT improves quality of life over pre-treatment, the applicant submitted the Vogl et al. (2017) study as evidentiary support. The study was a retrospective, multi-center study reporting outcome and safety after percutaneous isolated hepatic perfusion (PIHP) with Melphalan for patients with uveal melanoma and metastatic disease limited to the liver. Thirty-five PIHP treatments were performed in 18 patients (8 male, 10 female) at seven hospitals across the U.S and Germany between January 2012 and December 2016. Patients' life quality was assessed using four-point scale questionnaires to rate overall health and life quality after therapy, how much their health and quality of life had changed after therapy, and how pleased they were with PIHP. We note that the study used a subjective four-point measurement scale to determine quality-of-life used in the study. We question if a more objective assessment tool would be more helpful in evaluating a patient's quality of life. It is unclear if the survey questions were asked verbally, and by whom, or if the survey was answered in writing by the patient alone. As the study was not randomized and the patients' responses were not anonymous, we question if there may have been resulting response bias, or interviewer bias that would impact our ability to draw meaningful conclusions about a subjective measurement of improved quality of life. In addition, we note that the study utilized the Delcath Hepatic CHEMOSAT® Delivery System for Melphalan components as part of the treatment, and it is unclear if the technologies used in the study are the same as HEPZATO™ KIT, or what differences may exist between the technologies. We would be interested in information about any differences between Delcath's HEPZATO™ KIT and the technologies used in this study for PIHP with Melphalan.

We are inviting public comments on whether HEPZATO™ KIT meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for HEPZATO™ KIT.

g. Lantidra™ (donislecel-jujn (Allogeneic Pancreatic Islet Cellular Suspension for Hepatic Portal Vein Infusion))

CellTrans Inc. submitted an application for new technology add-on payments for Lantidra™ for FY 2025. According to the applicant, Lantidra™ is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target hemoglobin A1c (HbA1c) because of repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Per the applicant, Lantidra™ is used in conjunction with concomitant immunosuppression. The applicant asserted that the route of administration for Lantidra™ is infusion into the hepatic portal vein only. The applicant noted that following transplant, the patient is monitored for graft function and safety issues, including potential adverse reactions due to immunosuppression. The applicant stated that the primary mechanism of action for Lantidra™ is the secretion of insulin by the beta cells within the infused allogeneic islet of Langerhans, which are responsible for regulating blood glucose levels in response to glucose stimulation.

Please refer to the online application posting for Lantidra™, available at *https://mearis.cms.gov/public/publications/ntap/NTP231017H5N2T,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, Lantidra™ was granted approval for a Biologics License Application (BLA) from FDA on June 28, 2023, for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. According to the applicant, the technology was commercially available on January 8, 2024. The applicant stated that the approved manufacturing site for Lantidra™ is at the University of Illinois (UI) Health, UI in Chicago and time was needed to transfer islet cell transplant clinical protocols to the UI Health transplant division.

We note that under national coverage determination (NCD) 260.3.1 Islet Cell Transplantation in the Context of a Clinical Trial, Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial(s). Specifically, Medicare will cover transplantation of pancreatic islet cells, the insulin producing cells of the pancreas. Coverage may include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants. Because Lantidra™ may be covered by Medicare when it is used in the setting of a clinical trial, we will evaluate whether Lantidra™ is eligible for new technology add-on payments for FY 2025. We note that any payment made under the Medicare program for services provided to a beneficiary would be contingent on CMS' coverage of the item, and any restrictions on the coverage would apply.

The applicant stated that the recommended minimum dose is 5,000 equivalent islet number (EIN)/kg for the initial infusion, and 4,500 EIN/kg for subsequent infusion(s) in the same recipient. The maximum dose per infusion is dictated by the estimated tissue volume, which should not exceed 10 cc per infusion, and the total EIN present in the infusion bag (up to a maximum of $1 \times 10^{\wedge}6$ EIN per bag). A second infusion may be performed if the patient does not achieve independence from exogenous insulin within 1-year post-infusion or within 1-year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify Lantidra™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for Lantidra™ beginning in FY 2025.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered new for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Lantidra™ has not been assigned to the same MS–DRG when compared to an existing technology to achieve a therapeutic outcome. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Lantidra™ for the applicant's complete statements in support of its assertion that Lantidra™

is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	Yes	According to the applicant, whole pancreas transplant is the only treatment currently available for type 1 diabetes with severe hypoglycemia. The applicant stated that Lantidra™ uses the same mechanism of action as whole pancreas transplant, that is, glucose responsive secretion of insulin from allogeneic islet beta cells once infused into the hepatic portal vein.
Is the technology assigned to the same MS-DRG as existing technologies?	No	A whole (solid) pancreas transplant is assigned to MS-DRG 010. The procedure to infuse Lantidra™ is distinct (via administration into the hepatic portal vein). Applicable MS-DRGs may be 637 (Diabetes with MCC), 638 (Diabetes with CC), 639 (Diabetes without CC/MCC).
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	Whole pancreas transplant and Lantidra™ are the only treatment options for patients who have not achieved glycemic control despite intensive insulin treatment and diabetes management. Lantidra™ is the only FDA approved cellular therapy to treat patients with Type 1 diabetes.

We are inviting public comments on whether Lantidra™ is substantially similar to existing technologies and whether Lantidra™ meets the newness criterion.

With respect to the cost criterion, the applicant included the two most recent patient cases with charges of Lantidra™ billed by a hospital that administered the technology, based on that hospital's billing data file on the undiscounted costs. The applicant stated that it attempted to identify potential cases representing patients who may be eligible for Lantidra™ by searching the FY 2022 MedPAR and the 100 percent sample FY 2022 Standard Analytical Files (SAF) for cases reporting ICD–10–CM/PCS codes and MS–DRGs codes that were relevant to the FDA approved indication and administration of Lantidra™, however, it could not confirm if cost data from the two most recent patient cases were included in the FY 2022 MedPAR or SAF. As a result, the applicant provided the charges billed by the hospital for these two cases. The applicant stated that the MS–DRG coded for the two cases was MS–DRG 639 (Diabetes without CC/MCC). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $374,547, which exceeded the average case-weighted threshold amount of $32,311. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that Lantidra™ meets the cost criterion.

LANTIDRA™ COST ANALYSIS	
Data Source and Time Period	2022 Undiscounted Costs from Hospital Billing Paid by Sponsor
List of MS-DRGs	639 (Diabetes without CC/MCC)
Inclusion/exclusion criteria	The applicant included two most recent patient cases with charges of Lantidra™ billed by the hospital.
Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 10.00% to the standardized charges.
Charges added for the new technology	The applicant added the cost for Lantidra™ but did not convert the previous costs to charges for the new technology. The applicant did not add indirect charges related to the new technology.

We note the following concerns regarding the cost criterion. We note that the applicant did not remove any charges or indirect charges related to prior technology without providing further details. We are interested in

additional information regarding whether Lantidra™ would replace any prior technology. We are also interested in how the applicant estimated an inflation factor of 10.00 percent to apply to the standardized charges. With respect to the cases included in the cost analysis, we note that the applicant limited the cost analysis to the two most recent patient cases with charges of Lantidra™ billed by the hospital, which the applicant asserted were the best available data for the FY 2022 cost analysis. We note the MS–DRG coded for these two cases was MS–DRG 639 (Diabetes without CC/MCC). We are interested in information as to whether cases in other MS–DRGs would be potentially eligible for Lantidra™ and if these cases should also be included in the cost analysis by using appropriate inclusion/exclusion criteria based on reporting of ICD–10–CM/PCS codes.

We are inviting public comments on whether Lantidra™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Lantidra™ represents a substantial clinical improvement over existing technologies. The applicant asserted that patients with the indication of Type 1 diabetes characterized by hypoglycemic unawareness are at risk of severe hypoglycemia, complications, and death, if untreated. According to the applicant, when intensive insulin therapy is not sufficient for addressing symptoms of severe hypoglycemia, Lantidra™ infusion into the hepatic portal vein offers a safe and effective minimally invasive alternative with proven clinical outcomes, less complications, and similar overall costs to that of whole pancreas transplantation. The applicant also asserted that Lantidra™ provides a treatment option for patients unresponsive to, or ineligible for, currently available treatments because whole pancreas transplant, a currently available treatment, is associated with greater surgical and post-procedural risk than pancreatic islet transplantation. Additionally, the applicant asserted that due to procedural risks, some patients may not be appropriate surgical candidates for whole pancreas transplantation.[66] The applicant provided two patient testimonials, one study combining results of a Phase 1/2 and a Phase 3 clinical study to support these claims, as well as one background article.[67] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Lantidra™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
Lantidra™ improved quality of life for Type 1 diabetes patients.	Transcript of Patient Testimony_Lantidra™ website.docx. Transcript of Patient Testimony_FDA Advisory Committee Meeting.docx. CellTrans Inc., Cellular, Tissue, and Gene Therapies Advisory Committee Briefing Document. Lantidra™ (donislecel) for the Treatment of Brittle Type 1 Diabetes Mellitus. https://www.fda.gov/media/147529/download. April 15, 2021.
Lantidra™ patients achieved insulin independence.	CellTrans Inc., 2021, *op.cit.*
Lantidra™ patients showed a reduction in hypoglycemia episodes	CellTrans Inc., 2021, *op.cit.*
Lantidra™ patients showed improved HbA1c results.	CellTrans Inc., 2021, *op.cit.*
Lantidra™ SCI supportive Type 1 diabetes data: Islet transplantation significantly reduces CIMT	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Lantidra™ patients achieved insulin independence, improved HbA1c endpoints, had a reduction in hypoglycemia episodes and showed improved quality of life.	CellTrans Inc., 2021, *op.cit.*

[66] CellTrans Inc., Cellular, Tissue, and Gene Therapies Advisory Committee Briefing Document Lantidra™ (donislecel) for the Treatment of Brittle Type 1 Diabetes Mellitus. *https://www.fda.gov/media/147529/download* April 15, 2021. Pages 22 and 105.

[67] Background articles are not included in the following table but can be accessed via the online posting for the technology.

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After review of the information provided by the applicant, we have the following concerns regarding whether Lantidra™ meets the substantial clinical improvement criterion. We are interested in evidence on clinical outcomes based on comparison of Lantidra™ with currently available treatments, including whole pancreatic transplant or recent advances in glucose monitoring and insulin delivery systems that are FDA-approved. We also note that according to the summary of the long-term six-year follow-up of patients from the Lantidra™ clinical trials,[68] the number of evaluable patients was reduced from 30 at the baseline to 12 at year 6. We question whether the small number would impact the reliability of the conclusions about insulin independence and reduction in severe hypoglycemic events. Regarding the applicant's claim that Lantidra™ patients achieved insulin independence, improved HbA1c endpoints, had fewer hypoglycemia episodes, and experienced improved quality of life, the applicant stated that the Phase 1/2 and 3 trials had over 10 years of extended follow-up, but specific results on long-term efficacy appear to be provided only up to 6 years post- the last transplant.[69] We would be interested in learning about available results from any longer-term follow-up. In addition, we would be interested in data demonstrating that Lantidra™ results in improved clinical outcomes like reduced mortality to support an assessment of whether Lantidra™ represents a substantial clinical improvement.

We are inviting public comments on whether Lantidra™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Lantidra™.

h. AMTAGVI™ (lifileucel)

Iovance Biotherapeutics, Inc. submitted an application for new technology add-on payments for AMTAGVI™ (lifileucel) for FY 2025. According to the applicant, AMTAGVI™ is an one-time, single-dose autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for the treatment of advanced (unresectable or metastatic) melanoma comprised of a suspension of TIL for intravenous infusion. We note that Iovance Biotherapeutics submitted an application for new technology add-on payments for AMTAGVI™ for FY 2022 under the name lifileucel, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25272 through 25282) but withdrew the application prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979). We also note that the applicant submitted an application for AMTAGVI™ for FY 2023 under the name lifileucel, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28244 through 28257), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

Please refer to the online application posting for AMTAGVI™, available at *https://mearis.cms.gov/public/publications/ntap/NTP231012V8Y9J,* for additional detail describing the technology and the treatment of unresectable or metastatic melanoma.

With respect to the newness criterion, according to the applicant, AMTAGVI™ was granted Biologics License Application (BLA) approval from FDA on February 16, 2024 for treatment of adult patients with unresectable or metastatic melanoma previously treated with a programmed cell death protein 1 (PD–1) blocking antibody, and if B-raf proto-oncogene (BRAF) V600 mutation positive, a BRAF inhibitor with or without a mitogen-activated extracellular signal-regulated kinase (MEK) inhibitor. The applicant stated that AMTAGVI™ has received Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug, and Fast Track designations from FDA for the treatment of advanced melanoma. According to the applicant, AMTAGVI™ is expected to be commercially available within 30–40 days post-FDA approval due to the need for the physician to prescribe AMTAGVI™, the treatment center to receive approval from the patient's insurer and to schedule and surgically resect the patient's tumor tissue, the 22-day TIL manufacturing process, and shipment/invoicing of AMTAGVI™ to the treatment center for patient administration. We are interested in additional information regarding the delay in the technology's market availability, as it seems that the technology would need to be available for sale before a physician would be able to prescribe AMTAGVI™.

According to the applicant, AMTAGVI™ is provided as a single dose for infusion containing a suspension of TIL in up to four patient-specific intravenous (IV) infusion bag(s), with each dose containing $7.5 \times 10^{\wedge}9$ to $72 \times 10^{\wedge}9$ viable cells. The applicant further noted that there is a lymphodepleting regimen administered before infusion of AMTAGVI™, and, post-AMTAGVI™ infusion, an interleukin 2 (IL–2) infusion at 600,000 IU/kg is administered every 8 to 12 hours, for up to a maximum of 6 doses, to support cell expansion in vivo.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of AMTAGVI™: XW033L7 (Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7), and XW043L7 (Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7). The applicant stated that all diagnosis codes under the category C43 (Malignant melanoma of skin) may be used to currently identify the indication for AMTAGVI™ under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that AMTAGVI™ is not substantially similar to other currently available technologies because TIL immunotherapy with AMTAGVI™ has a novel and unique mechanism of action which delivers a highly customized, personalized, and targeted, single-infusion treatment for advanced melanoma, and AMTAGVI™ is the first and only TIL immunotherapy approved for the treatment of advanced (unresectable or metastatic) melanoma, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for AMTAGVI™ for the applicant's complete statements in support of its assertion that AMTAGVI™ is not substantially similar to other currently available technologies.

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[68] CellTrans, Inc. 2021, Table 20, p. 60.

[69] Ibid.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	AMTAGVI™ does not use the same or a similar mechanism of action as any other existing technology, including currently available products used as earlier treatment of advanced melanoma and included in the 2022 100% Medicare Provider Analysis and Review (MedPAR) Limited Data Set. The currently available first- and second-line treatments for advanced melanoma include kinase inhibitors (BRAF and MEK inhibitors), immune checkpoint inhibitors (ICIs) (anti-CTLA-4 antibody and anti-PD-1 antibody), and the recently approved ICI and anti-LAG-3 combination. There are no approved treatment options for patients with advanced melanoma previously treated with ICI therapy. Some patients with disease progression after receiving an anti-PD-1 antibody and a targeted therapy may receive high-dose IL-2 or cytotoxic agents.[70] TIL immunotherapy with AMTAGVI™ has a novel and unique mechanism of action which delivers a highly customized, personalized, and targeted single infusion treatment for advanced melanoma. AMTAGVI™ TIL immunotherapy involves autologous T-cells directly isolated from the patient's tumor tissue and expanded ex vivo. Following the infusion of AMTAGVI™, the TIL migrates back into the patient's tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens. TIL have clear differentiation and advantage in treatment of solid tumors (for example, unresectable or metastatic melanoma) including tumor recognition, personalized, polyclonal and neoantigen-specific.[71,72,73,74] TIL immunotherapy with one-time treatment of AMTAGVI™ is also highly differentiated from currently approved chimeric antigen receptor (CAR) T-cell therapies that treat liquid tumors. While other types of adoptive cell therapy, including CAR T-cell therapies, utilize circulating T-cells from the blood, TIL therapy harvests neoantigen-directed T-cells that are isolated from a tumor biopsy. Thus, the unique mechanism of action of AMTAGVI™ TIL immunotherapy and the distinguishing criteria demonstrate that AMTAGVI™ is not substantially similar to other currently available therapies and/or technologies.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There are no cases assigned to any MS-DRG in the 2022 MedPAR data representing advanced melanoma cases treated with a TIL immunotherapy. CMS has finalized the assignment of AMTAGVI™ ICD-10-PCS procedure codes to Pre-MDC MS-DRG 018 where CAR T-cell, non-CAR T-cell and other immunotherapies map. Cases where AMTAGVI™ is administered will be distinctly identified by lifileucel-specific ICD-10-PCS administration codes, XW033L7 and XW043L7. In the FY 2022 IPPS final rule, CMS finalized its proposal to assign existing procedure codes describing CAR T-cell, non-CAR T-cell and other immunotherapies to Pre-MDC MS-DRG 018 and to modify the title to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies that would be assigned to this MS-DRG (for example, introduction of lifileucel

[70] Olson D, et al. Immune checkpoint inhibitors (ICI) treatment after progression on anti-PD-1 therapy in advanced melanoma: a systematic literature review. National Comprehensive Care Network (NCCN) Annual Conference, Poster. March–April 2023.

[71] Schumacher TN, Schreiber RD: Neoantigens in cancer immunotherapy. Science 348:69–74, 2015.

[72] Simpson-Abelson MR, Hilton F, Fardis M, et al: Iovance generation-2 tumor-infiltrating lymphocyte (TIL) product is reinvigorated during the manufacturing process. Ann Ocol 31:S645–S671, 2020 (suppl 4).

[73] Raskov H, et al. British Journal of Cancer (2021) 124:359–367, *https://doi.org/10.038/s41416-020-01048-4.*

[74] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

		immunotherapy into peripheral vein, percutaneous approach, new technology group 7) in addition to CAR T-cell therapies. The applicant stated that in its final decision, CMS noted the clinical similarities with respect to the administration of CAR T-cell therapies and AMTAGVI™, the complexity of the conditions in which they are treating, and resource utilization. The applicant stated that CMS specifically included the AMTAGVI™ ICD-10-PCS codes in the FY 2022 IPPS final rule table of codes mapped to Pre-MDC MS-DRG 018, effective with the beginning of FY 2022. The AMTAGVI™ ICD-10-PCS codes were also published in Table 6B – New Procedure Codes and reflect mapping to Pre-MDC MS-DRG 018. Importantly, patient cases where AMTAGVI™ is administered will be uniquely identified by the ICD-10-PCS codes XW033L7 and XW043L7 and will be mapped to Pre-MDC MS-DRG-018.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	AMTAGVI™ involves the treatment of patients with advanced (unresectable or metastatic) melanoma previously treated with systemic therapy and, AMTAGVI™ is the first and only FDA-approved post-ICI and post-BRAF/MEK therapy for this challenging-to-treat patient population across all classes of medicines, including small molecules, protein biologics, cellular therapy, etc. Advanced melanoma is identified by ICD-10-CM codes that are distinct from diagnosis codes used for the patient populations with hematologic malignancies treated by currently available CAR T-cell therapies, that is, large B-cell lymphoma, relapsed/refractory mantle cell lymphoma, and relapsed/ refractory multiple myeloma. For clarification, Stage III melanoma that cannot be completely surgically resected is considered as advanced unresectable melanoma. Although it is not metastatic, advanced unresectable stage III melanoma is treated similarly to metastatic or Stage IV melanoma.

We are inviting public comments on whether AMTAGVI™ is substantially similar to existing technologies and whether AMTAGVI™ meets the newness criterion.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR file using different combinations of ICD–10–CM codes, ICD–10–PCS codes, and/or inpatient length-of-stay (LOS) of 10 or more days. The applicant explained that it used different combinations to demonstrate four different cohorts that may be eligible for the technology. According to the applicant, eligible cases for AMTAGVI™ will be mapped to Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies). For each analysis, the applicant used the FY 2025 new technology add-on payments threshold for Pre-MDC MS–DRG 018 for all identified cases. Each analysis followed the order of operations described in the table later in this section.

For the first analysis, the applicant searched for potential cases for the following combination of ICD–10–CM diagnosis/procedure codes: any melanoma and metastasis diagnosis codes and any cytokine interleukin-2 (IL–2) or chemotherapy procedure codes. Please see the online posting for AMTAGVI™ for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 176 claims mapping to 16 MS–DRGs, with each MS–DRG representing 6.3 percent of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,150,682, which exceeded the average case-weighted threshold amount of $1,374,450.

For the second analysis, the applicant searched for potential cases for the following ICD–10–CM diagnosis/procedure codes in combination with an inpatient LOS of 10 or more days: any melanoma and metastasis diagnosis codes and any cytokine interleukin-2 (IL–2) or chemotherapy procedure codes. Please see the online posting for AMTAGVI™ for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 77 claims mapping to seven MS–DRGs, with each MS–DRG representing 14.3 percent of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,207,367, which exceeded the average case-weighted threshold amount of $1,374,450.

For the third analysis, the applicant searched for potential cases for the following combination of ICD–10–CM diagnosis/procedure codes: a code describing primary or admitting diagnosis of melanoma and a metastasis diagnosis code. Please see the online posting for AMTAGVI™ for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 735 claims mapping to 64 MS–DRGs, with each MS–DRG representing 3.4 percent to 1.5 percent of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,017,903, which exceeded the average case-weighted threshold amount of $1,374,450.

For the fourth analysis, the applicant searched for potential cases for the following combination of ICD–10–CM diagnosis/procedure codes: a code describing any diagnosis of melanoma and a metastasis diagnosis code. Please see the online posting for AMTAGVI™

for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 6,648 claims mapping to 358 MS–DRGs, each MS–DRG representing 0.2 percent to 6.7 percent of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,018,905, which exceeded the average case-weighted threshold amount of $1,374,450.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that AMTAGVI™ meets the cost criterion.

AMTAGVI™ COST ANALYSIS[75]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	Analyses 1,2,3, and 4—All diagnosis codes under the categories: C43 (Malignant melanoma of skin) D03 (Melanoma in situ) C78 (Secondary malignant neoplasm of respiratory and digestive organs) C79 (Secondary malignant neoplasm of other and unspecified sites)
List of ICD-10-PCS codes	Analyses 1 and 2: 3E03002 (Introduction of high-dose interleukin-2 into peripheral vein, open approach) 3E03003 (Introduction of low-dose interleukin-2 into peripheral vein, open approach) 3E03005 (Introduction of other antineoplastic into peripheral vein, open approach) 3E03302 (Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach) 3E03303 (Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach) 3E03305 (Introduction of other antineoplastic into peripheral vein, percutaneous approach) 3E04002 (Introduction of high-dose interleukin-2 into central vein, open approach) 3E04003 (Introduction of low-dose interleukin-2 into central vein, open approach) 3E04005 (Introduction of other antineoplastic into central vein, open approach) 3E04302 (Introduction of high-dose interleukin-2 into central vein, percutaneous approach) 3E04303 (Introduction of low-dose interleukin-2 into central vein, percutaneous approach) 3E04305 (Introduction of other antineoplastic into central vein, percutaneous approach) Analyses 3 and 4: N/A
List of MS-DRGs	Analyses 1, 3, and 4: For the list of MS-DRGs, see the online posting for AMTAGVI™. Analysis 2: 193 (Simple Pneumonia and Pleurisy with MCC) 389 (G.I. Obstruction with CC) 054 (Nervous System Neoplasms with MCC) 542 (Pathological Fractures and Musculoskeletal and Connective Tissue Malignancy with MCC) 802 (Other O.R. Procedures of The Blood and Blood Forming Organs with MCC) 840 (Lymphoma and Non-Acute Leukemia with MCC) 844 (Other Myeloproliferative Disorders or Poorly Differentiated Neoplastic Diagnoses with CC)
Inclusion/exclusion criteria	Analysis 1: The applicant selected claims based on the codes listed previously as it believes this list represents patients with a principal or secondary ICD-10-CM diagnosis code representing cases with primary or secondary diagnosis of melanoma with metastasis and treatment using either IL-2 or chemotherapy. The applicant stated this analysis represents a patient population that is eligible for treatment with AMTAGVI™ based on the indication. Analysis 2: The applicant selected claims based on the codes listed previously as it believes this list represents patients with a principal or secondary ICD-10-CM diagnosis code representing cases with primary or secondary diagnosis of melanoma with metastasis and treatment using either IL-2 or chemotherapy, in combination with an inpatient length of stay (LOS) of 10 or more days. The applicant stated this analysis represents a patient population that is eligible for treatment with AMTAGVI™ based on the indication, and patients who stay 10 or more days in the hospital more closely approximate the expected resource intensity for the AMTAGVI™ regimen. Analysis 3: The applicant selected claims based on the codes listed previously as it believes this list represents patients with a primary or admitting diagnosis of melanoma with secondary diagnosis of metastasis, but with no IL-2 or chemotherapy treatment requirement. The applicant stated this analysis illustrates a likely patient population that will be treated with AMTAGVI™ by focusing on a narrow set of melanoma cases and removing the requirement that the patient be receiving IL-2 or chemotherapy. Analysis 4: The applicant selected claims based on the codes listed previously as it believes this list represents patients with any diagnosis of melanoma with secondary diagnosis of metastasis, but with no treatment requirement. The applicant stated this analysis illustrates a likely patient population that will be treated with AMTAGVI™ by focusing on a full set of melanoma cases and removing the requirement that the patient be receiving IL-2 or chemotherapy.
Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology. The applicant indicated that no technology is being replaced.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.90% to the standardized charges, based on the two-year inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.

AMTAGVI™ COST ANALYSIS[75]	
Charges added for the new technology	The applicant added charges for the new technology by dividing the Wholesale Acquisition Cost (WAC) of the new technology by an estimated cost-to-charge ratio of 0.2669 for CAR-T therapies. The applicant stated that this cost-to-charge ratio is greater than the national average cost-to-charge ratio of 0.18 for drugs from the FY 2024 IPPS/LTCH PPS final rule, resulting in a lower estimated charges for the cost criterion analysis. The applicant did not add indirect charges related to the new technology.

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We are inviting public comments on whether AMTAGVI™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that AMTAGVI™ represents a substantial clinical improvement over existing technologies because the efficacy and safety profile of the single infusion of AMTAGVI™ TIL immunotherapy addresses an important unmet need in the advanced (unresectable or metastatic) melanoma population who lack effective or approved treatment options after being previously treated with ICI therapy. The applicant asserts that the clinically meaningful and durable activity of AMTAGVI™ represents substantial clinical improvement over published outcomes for chemotherapy. The applicant provided four studies to support these claims, as well as 22 background articles about treatments for advanced melanoma.[76]

The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for AMTAGVI™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[75] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

[76] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
AMTAGVI™ will be the first and only FDA-approved therapy for patients with advanced melanoma who relapse on or do not tolerate current therapies	Chesney J, et al. J Immunother Cancer 2022; 10:e005755. doi:10.1136/jitc-2022-005755 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
A single infusion of AMTAGVI™ has produced clinically meaningful and durable responses in patients with advanced melanoma who progress after ICI or targeted therapy	Chesney J, et al. J Immunother Cancer 2022; 10:e005755. doi:10.1136/jitc-2022-005755 Sarnaik A, et al. Oral presentation. 37th Annual Meeting and Pre-Conference Programs. Society for Immunotherapy of Cancer (SITC). November 10, 2022. Hamid O, et al. Melanoma Bridge 2022. December 1-3, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Patients with advanced melanoma previously treated with ICI therapy will have substantially improved objective response rate (ORR) compared with patients treated with currently available therapies	Chesney J, et al. J Immunother Cancer 2022; 10:e005755. doi:10.1136/jitc-2022-005755 Sarnaik A, et al. Oral presentation. 37th Annual Meeting and Pre-Conference Programs. Society for Immunotherapy of Cancer (SITC). November 10, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
AMTAGVI™ is a viable therapeutic option for patients with advanced melanoma with a safety profile consistent with the underlying advanced disease and the known profiles of nonmyeloablative lymphodepleting (NMA-LD) and IL-2	Chesney J, et al. J Immunother Cancer 2022; 10:e005755. doi:10.1136/jitc-2022-005755 Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. J Clin Oncol. 2021;39(24):2656-66. doi:10.1200/JCO.21.00612. (Published online first: 2021/05/13). The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

After review of the information provided by the applicant, we have the following concerns regarding whether AMTAGVI™ meets the substantial clinical improvement criterion.

In support of its application, the applicant provided data from the C–144–01 study, an ongoing phase two multicenter study (NCT02360579) to assess the efficacy and safety of autologous TIL in patients with stage IIIc–IV metastatic melanoma, which consisted of: Cohort 1 (n = 30 generation 1 no-cryopreserved TIL product); Cohort 2 (n = 66 generation 2 cryopreserved TIL product); Cohort 3 (a sub-sample of n = 10 from Cohorts 1, 2, and 4); and Cohort 4 (n = 75 generation 2 cryopreserved TIL product). In regard to the sample studied (Cohorts 2 & 4 combined) by Chesney et al. (2022),[77] similar to concerns raised in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25281), we continue to question the appropriateness of combining Cohorts 2 and 4 together. Furthermore, similar to concerns raised in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28256 through 28257), we note that in the study of Chesney et al. (2022), 54 percent of the sample size included males with a median age of 56; data on race, ethnicity, and other demographics are not presented. Given that the average age of Medicare beneficiaries is substantially older, and that Medicare beneficiaries often have multiple comorbidities, we question whether the sample evaluated is appropriately representative of the Medicare population and whether this sample has a disease burden similar to that seen in Medicare beneficiaries.[78,79,80] Thus, similar to concerns raised in the FY 2023 IPPS/LTCH PPS proposed rule (87

[77] Chesney J, et al. J Immunother Cancer 2022 ;10:3005755.Doi:10.1136/jitc-2022–005755.

[78] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Medicare_Beneficiary_Characteristics.*

[79] Centers for Medicare and Medicaid Services. Chronic Conditions among Medicare Beneficiaries, Chartbook, 2012 Edition. Baltimore, MD. 2012. *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf.*

[80] Cher, B., Ryan, A. M., Hoffman, G. J., & Sheetz, K. H. (2020). Association of Medicaid Eligibility With Surgical Readmission Among Medicare Beneficiaries. JAMA network open, 3(6), e207426. *https://doi.org/10.1001/jamanetworkopen.2020.7426.*

FR 28256 through 28257), we are concerned that the findings may not be generalizable to Medicare beneficiaries. Furthermore, as discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28256), we continue to question whether the patient sample evaluated in the Sarnaik et al. (2021) [81] study is appropriately representative of the Medicare population and whether this sample has a disease burden similar to that seen in Medicare beneficiaries.

Second, similar to concerns raised in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25279 through 25282) and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28256 through 28257), we continue to note that while multiple background studies were provided in support of the applicant's claims for substantial clinical improvement, those that evaluate AMTAGVI™ are based solely on the C–144–01 trial. The background studies focus primarily on describing the limitations of other therapies rather than supporting the role of AMTAGVI™, and no direct comparisons to other existing therapies such as targeted therapies with combination BRAF plus MEK inhibitors or nivolumab plus ipilimumab were provided. Therefore, we would be interested in additional information comparing AMTAGVI™ to existing treatments (for example, evidence comparing AMTAGVI™ phase two studies to the phase two studies of existing or approved treatments by using meta-analysis after systematic review, or evidence based on retrospective cohort studies of the relevant patients to assess whether AMTAGVI™ had significantly different impact on any outcomes compared to existing or approved treatments).

Third, similar to concerns raised in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25279 through 25282), and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28256 through 28257), we note that the Chesney et al. (2022) [82] study uses a surrogate endpoint, ORR, which combines the results of complete and partial responders; we question whether this correlates to improvement in clinical outcomes such as overall survival (OS).

Finally, similar to concerns raised in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28256 through 28257), we note that according to the applicant, high-dose IL–2 has been used to treat metastatic melanoma in the past and is given as a post-treatment to AMTAGVI™. According to the applicant, the occurrence of grade 3 and 4 treatment-emergent adverse events (TEAEs) was early and consistent with the lymphodepletion regimen (NMA–LD) and known profile of IL–2. If AMTAGVI™ is always given in conjunction with the pre- and post-treatments, we question how it is possible to determine the cause of the TEAEs which are categorized as severe based on the Common Terminology Criteria for Adverse Events v4.03. We continue to question whether the effect seen in C–144–01 is due to AMTAGVI™ itself or due to other factors such as the use of IL–2, general changes in medical practice over time, and the specific sample identified for the trial at hand.

We are inviting public comments on whether AMTAGVI™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for AMTAGVI™.

i. Lyfgenia™ (lovotibeglogene autotemcel)

Bluebird bio, Inc. submitted an application for new technology add-on payments for Lyfgenia™ (lovotibeglogene autotemcel) for FY 2025. According to the applicant, Lyfgenia™ is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease (SCD) and a history of vaso-occlusive events (VOE). Lyfgenia™, administered as a single-dose intravenous infusion, consists of an autologous cluster of differentiation 34+ (CD34+) cell-enriched population from patients with SCD that contains hematopoietic stem cells (HSCs) transduced with BB305 lentiviral vector (LVV) encoding the β-globin gene (β^{A-T87Q}-globin gene), suspended in a cryopreservation solution. The applicant explained that Lyfgenia™ is designed to add functional copies of a modified form of the β^{A-T87Q}-globin gene into a patient's own HSCs, which allows their red blood cells to produce an anti-sickling adult hemoglobin (HbA^{T87Q}), to reduce or eliminate downstream complications of SCD.

Please refer to the online application posting for Lyfgenia™, available at *https://mearis.cms.gov/public/publications/ntap/NTP231013X3AK8,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, Lyfgenia™ was granted Biologics License Application (BLA) approval from FDA on December 8, 2023, for the treatment of patients 12 years of age or older with SCD and a history of VOEs. The applicant stated that it anticipates that Lyfgenia™ will become available for sale on April 16, 2024 and that the first commercial claim for Lyfgenia™ will occur within approximately 130 days post-FDA approval to allow for the one-time activity to commercially qualify the contract manufacturer organization (CMO), followed by apheresis of the first patient at the qualified treatment center (QTC), where the personalized starting material will be shipped to the CMO for drug product manufacturing, release testing, and shipment of final product to the QTC for the one-time infusion. We are interested in additional information regarding the delay in the technology's market availability, as it appears that the technology would need to be available for sale prior to the enrollment of the first patient at the QTC. According to the applicant, Lyfgenia™ is provided in infusion bags containing 1.7 to 20×10^6 cells/mL (1.4 to 20×10^6 CD34+ cells/mL) in approximately 20 mL of solution and is supplied in one to four infusion bags. Per the applicant, the minimum dose is 3.0×10^6 CD34+ cells/kg patient weight.

According to the applicant, as of October 1, 2023, there are currently two ICD–10–PCS procedure codes to distinctly identify the intravenous administration of Lyfgenia™: XW133H9 (Transfusion of lovotibeglogene autotemcel into central vein, percutaneous approach, new technology group 9) and XW143H9 (Transfusion of lovotibeglogene autotemcel into peripheral vein, percutaneous approach, new technology group 9). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for Lyfgenia™ under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Lyfgenia™ is not substantially

[81] Sarnaik A, et al. Lifileucel, a tumor-infiltrating lymphocyte therapy, in metastatic melanoma. J Clin Oncol. 2021;39(24):2656–66. doi:10.1200/JCO.21.00612 (Published online first: 2021/05/13).

[82] Chesney J, et al. J Immunother Cancer 2022; 10:3005755.Doi:10.1136/jitc–2022–005755.

similar to other currently available technologies, because Lyfgenia™ has a distinct mechanism of action, which converts SCD at the genetic, cellular, and physiologic level to a non-sickling phenotype through the expression of the gene therapy-derived antisickling β^{A-T87Q}-globin gene, and that therefore, the technology meets the newness criterion. Additionally, the applicant stated Lyfgenia™ is not substantially similar to other currently available therapeutic approaches indicated for SCD or to any drug therapy assigned to any MS–DRG in the 2022 MedPAR data.

The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Lyfgenia™ for the applicant's complete statements in support of its assertion that Lyfgenia™ is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Lyfgenia™'s distinct mechanism of action and distinguishing criteria demonstrate that it is not substantially similar to other currently available therapeutic approaches for the treatment of SCD or any drug therapy assigned to any MS-DRG in the 2022 MedPAR data. With its unique mechanism of action, Lyfgenia™ seeks to convert SCD at the genetic, cellular, and physiologic level to a non-sickling phenotype through the expression of the gene therapy-derived anti-sickling β^{A-T87Q}-globin; thus, reducing or eliminating downstream complications. Treatment with Lyfgenia™ involves isolation of CD34+ HSC, ex vivo transduction of the cells with BB305 LVV to introduce the β^{A-T87Q}-globin gene, and then intravenous infusion of the genetically-modified autologous cells into the patient. Lovo-cel is substantially differentiated from allo-HSCT, where the broad utility is significantly limited in the SCD population by age of patient, limited availability of HLA-matched sibling donors, as well as transplant risks. Lyfgenia™'s gene addition technology, described previously, is distinct from the investigational gene-edited technology of exagamglogene autotemcel (Casgevy™), which identifies the erythroid-specific enhancer region of BCL11A in CD34+ cells and cuts the gene using Cas9 and guide RNA to reduce the expression of BCL11A. And, finally, Lyfgenia™ is a distinct drug product with a discrete clinical development program from bluebird bio's Zynteglo™ (betibeglogene autotemcel, or beti-cel), a gene therapy approved by the FDA on August 17, 2022, for the treatment of adult and pediatric patients with β-thalassemia who require regular RBC transfusions.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There are no patient cases assigned to any MS-DRG in the 2022 MedPAR data representing SCD cases treated with a gene therapy. Effective October 1, 2023, there are two unique ICD-10-PCS codes to identify administration of Lyfgenia™ in the inpatient setting: XW133H9 and XW143H9. These two Lyfgenia™-specific ICD-10-PCS codes map to Pre-MDC DRGs 016 (Autologous Bone Marrow Transplant with MCC/CC) and 017 (Autologous Bone Marrow Transplant without MCC/CC. Thus, all patient claims where Lyfgenia™ is administered will be distinguishable from other therapies that may be assigned to Pre-MDC MS-DRGs 016 and 017.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	Patients with SCD treated with currently approved therapies are identified by existing ICD-10-CM diagnosis codes. Upon FDA approval, Lyfgenia™ has the potential to offer these same patients transformative clinical benefits to improve the hemolytic anemia and VOEs that characterize SCD, without the current limitations of allogenic hematopoietic stem cell transplantation (allo-HSCT) and addresses red blood cell sickling at the genetic level while abrogating the need for a well-matched donor. Currently disease-modifying therapies address acute manifestation of disease but do not address the underlying genetic cause of the disease and may require lifelong use and potential for inadherence. While allo-HSCT is a potentially curative option, outcomes worsen with age, and broad utility is limited by a paucity of matched sibling donors, as well as transplant risks. Cases for patients treated with Lyfgenia™, a personalized, one-time, potentially transformative gene therapy, will be identified by the SCD ICD-10-CM diagnosis codes and the unique ICD-10-PCS procedure codes approved by CMS for identification of Lyfgenia™ administration: XW133H9 and XW143H9.

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We note that Lyfgenia™ may have the same or similar mechanism of action to Casgevy™, for which we also received an application for new technology add-

on payments for FY 2025. Lyfgenia™ and Casgevy™ are both gene therapies using modified autologous CD34+ hematopoietic stem and progenitor cell (HSPC) therapies administered via stem cell transplantation for the treatment of SCD. Both technologies are autologous, ex-vivo modified hematopoietic stem-cell biological products. As previously discussed, Casgevy™ was approved by FDA for this indication on December 8, 2023. For these technologies, patients are required to undergo CD34+ HSPC mobilization followed by apheresis to extract CD34+ HSPCs for manufacturing and then myeloablative conditioning using busulfan to deplete the patient's bone marrow in preparation for the technologies' modified stem cells to engraft to the bone marrow. Once engraftment occurs for both technologies, the patient's cells start to produce a different form of hemoglobin to reduce the amount of sickling hemoglobin. Further, both technologies appear to map to the same MS–DRGs, MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) and 017 (Autologous Bone Marrow Transplant without CC/MCC), and to treat the same or similar disease (sickle cell disease) in the same or similar patient population (patients 12 years of age and older who have a history of vaso-occlusive events). Accordingly, as it appears that Lyfgenia™ and Casgevy™ may use the same or similar mechanism of action to achieve a therapeutic outcome (that is, to reduce the amount of sickling hemoglobin to reduce and prevent VOEs associated with SCD), would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We note that if we determine that this technology is substantially similar to Casgevy™, we believe the newness period would begin on December 8, 2023, the date both Lyfgenia™ and Casgevy™ received FDA approval for SCD. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether Lyfgenia™ and Casgevy™ are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether Lyfgenia™ meets the newness criterion, including whether Lyfgenia™ is substantially similar to Casgevy™ and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR using different ICD–10–CM codes to identify potential cases representing patients who may be eligible for Lyfgenia™. Per the applicant, Lyfgenia™ is intended for patients who have not already undergone Allogeneic Bone Marrow Transplant or Autologous Bone Marrow Transplant. The applicant explained that it used different ICD–10–CM codes to demonstrate different cohorts of SCD patients that may be eligible for the technology.

According to the applicant, eligible cases for Lyfgenia™ will be mapped to either Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC) or 017 (Autologous Bone Marrow Transplant without CC/MCC). For each cohort, the applicant performed two sets of analyses using either the FY 2025 new technology add-on payments threshold for Pre-MDC MS–DRG 016 or Pre-MDC MS–DRG 017 for all identified cases. We note that the FY 2025 new technology add-on payments thresholds for both Pre-MDC MS–DRG 016 and Pre-MDC MS–DRG 017 are $182,491. Each analysis followed the order of operations described in the table later in this section.

For the primary cohort, the applicant searched for an appropriate group of patients with any ICD–10–CM diagnosis code for SCD with crisis. Please see the online posting for Lyfgenia™ for the complete list of ICD–10–CM codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 12,357 claims mapping to 167 MS–DRGs, including MS–DRGs 811 and 812 (Red Blood Cell Disorders with MCC and without MCC, respectively) representing 76.0 percent of total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $11,677,887, which exceeded the average case-weighted threshold amount of $182,491.

For the sensitivity 1 cohort, the applicant searched for a narrower cohort of patients with the admitting or primary ICD–10–CM diagnosis codes of Hemoglobin-SS (Hb-SS) SCD with crisis for the most common genotype of SCD. Please see the online posting for Lyfgenia™ for a complete list of ICD–10–CM codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 10,987 claims mapping to 160 MS–DRGs, including MS–DRGs 811 and 812 (Red Blood Cell Disorders with and without MCC, respectively) representing 75.1 percent of total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $11,680,025, which exceeded the average case-weighted threshold amount of $182,491.

For the sensitivity 2 cohort, the applicant searched for a broader cohort of patients with the primary or secondary ICD–10–CM diagnosis codes for SCD with or without crisis. Please see the online posting for Lyfgenia™ for a complete list of ICD–10–CM codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 17,120 claims mapping to 453 MS–DRGs, including MS–DRGs 811 and 812 (Red Blood Cell Disorders with and without MCC, respectively) representing 56.3 percent of total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $11,681,718, which exceeded the average case-weighted threshold amount of $182,491.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant maintained that Lyfgenia™ meets the cost criterion.

LYFGENIA™ COST ANALYSIS[83]	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	Please see the online posting for Lyfgenia™ for a complete list of ICD-10-CM codes provided by the applicant.
List of MS-DRGs	Please see the online posting for Lyfgenia™ for a list of included MS-DRGs provided by the applicant.
Inclusion/ exclusion criteria	Primary cohort: The applicant selected claims based on the codes provided by the applicant in the online posting as it believes this list represents patients with any ICD-10-CM diagnosis code representing SCD with crisis. Sensitivity 1 cohort: The applicant selected claims based on the codes provided by the applicant in the online posting as it believes this list represents patients with an admitting or primary ICD-10-CM diagnosis code of Hb-SS disease with crisis, the most common genotype of SCD. Sensitivity 2 cohort: The applicant selected claims based on the codes provided by the applicant in the online posting as it believes this list represents patients with a primary or secondary ICD-10-CM diagnosis code of SCD with or without crisis. The applicant made the same exclusions for all three scenarios. The applicant excluded claims assigned to MS-DRG 014 (Allogenic Bone Marrow Transplant), 016 (Autologous Bone Marrow Transplant with CC/MCC), or 017 (Autologous Bone Marrow Transplant without CC/MCC) as the technology is intended for patients who have not already undergone allogeneic or autologous bone marrow transplant.
Charges removed for prior technology	The applicant did not remove any charges for the prior technology. The applicant stated that in the case of Lyfgenia™, the inpatient hospital charges for myeloablative conditioning and Lyfgenia™ infusion will exceed any current charges for drugs and ancillary services.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.90% to the standardized charges, based on the two-year inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by an estimated cost-to-charge ratio of 0.2669 for CAR T-cell therapies. The applicant stated that this cost-to-charge ratio is greater than the national average cost-to-charge ratio of 0.18 for drugs from the FY 2024 IPPS/LTCH PPS final rule, resulting in a lower estimated charges for the cost criterion analysis. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether Lyfgenia™ meets the cost criterion. With regard to the substantial clinical improvement criterion, the applicant asserted that Lyfgenia™ represents a substantial clinical improvement over existing technologies, because Lyfgenia™ is a one-time administration gene therapy that uniquely impacts the pathophysiology of SCD at the genetic level and offers the potential for stable, durable production of anti-sickling hemoglobin HbA^{T87Q}, with approximately 85 percent of RBCs producing HbA^{T87Q}, leading to complete resolution of severe VOEs in patients with SCD through 5.5 years of follow-up. The applicant asserted that for these reasons Lyfgenia™ is a much-needed treatment option for a patient population ineligible for allo-HSCT or without a matched related donor and significantly improves health-related quality of life. The applicant provided seven studies on Lyfgenia™ to support these claims, as well as 22 background articles about SCD and its current treatments.[84] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Lyfgenia™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[83] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

[84] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.	
Applicant statements in support	**Supporting evidence provided by the applicant**
Lyfgenia™ will provide a much-needed SCD treatment option, including for patients ineligible for allo-HSCT and for patients without a matched related donor.	Kanter J, et al. Lovo-cel gene therapy for sickle cell disease: treatment process evolution and outcomes in the initial groups of the HGB-206 study. Am J Hematol. 2023 Jan;98(1):11-22. Kanter J, et al. N Engl J Med. 2022;386:617-628. The applicant also provided a supplementary attachment and background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.	
Applicant statements in support	**Supporting evidence provided by the applicant**
One-time administration of Lyfgenia™ gene therapy in patients with SCD impacts the pathophysiology of SCD (polymerization of HbS) at the genetic level, intended to halt SCD progression.	Kanter J, et al. 65th ASH Annual Meeting and Exposition. December 9-12, 2023. Abstract 1051. Oral presentation (December 11th). Kanter J, et al. N Engl J Med. 2022;386:617-628. Tisdale JF, et al. Polyclonality strongly correlates with biological outcomes and is significantly increased following improvements to the phase 1/2 HGB-206 protocol and manufacturing of LentiGlobin for sickle cell disease (SCD; bb1111) gene therapy (GT). American Society of Hematology (ASH) Annual Meeting 2021, Abstract #561. Oral presentation. Blood. 2021;138 (Supplement 1):561. The applicant also provided a supplementary attachment and background information to support this claim, which can be accessed via the online posting for the technology.
Lyfgenia™ efficacy and safety data from Study HGB-206 Group C present an acceptable risk-benefit profile for patients with SCD, with clinically meaningful improvements in health-related quality of life (HRQoL)	Tisdale JF, et al. Updated results from HGB-206 lentiglobin for sickle cell disease gene therapy study: Group C data and Group A AML case investigation. American Society of Gene and Cell Therapy (ASGCT) Annual Meeting 2021, Abstract #196. Molecular Therapy. 2021;29:4S1. Walters MC, et al. Lovo-cel (bb1111) gene therapy for sickle cell disease: updated clinical results and investigations into two cases of anemia from group C of the phase 1/2 HGB-206 study. ASH 2022 Congress. Abstract #11; presentation. Tisdale JF, et al. Polyclonality strongly correlates with biological outcomes and is significantly increased following improvements to the phase 1/2 HGB-206 protocol and manufacturing of LentiGlobin for sickle cell disease (SCD; bb1111) gene therapy (GT). American Society of Hematology (ASH) Annual Meeting 2021, Abstract #561. Oral presentation. Blood. 2021;138 (Supplement 1):561. Kanter J, et al. 65th ASH Annual Meeting and Exposition. December 9-12, 2023. Abstract 1051. Oral presentation (December 11th). Kanter J, et al. N Engl J Med. 2022;386:617-628.

	Walters MC, et al. Sustained improvements in patient-reported quality of life up to 24 months post-treatment with Lentiglobin for sickle cell disease (bb1111) gene therapy. American Society of Hematology (ASH) Annual Meeting 2021. Blood. 2021;138(1):7. The applicant also provided a supplementary attachment and background information to support this claim, which can be accessed via the online posting for the technology.
Patients with SCD experienced complete resolution of sVOEs after the one-time treatment of Lyfgenia™, a personalized gene therapy; overall median rate of VOEs was zero (0) per year.	Kanter J, et al. N Engl J Med. 2022;386:617-628. Kanter J, et al. 65th ASH Annual Meeting and Exposition. December 9-12, 2023. Abstract 1051. Oral presentation (December 11th). Walters MC, et al. Lovo-cel (bb1111) gene therapy for sickle cell disease: updated clinical results and investigations into two cases of anemia from group C of the phase 1/2 HGB-206 study. ASH 2022 Congress. Abstract #11; presentation. The applicant also provided a supplementary attachment and background information to support this claim, which can be accessed via the online posting for the technology.

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After review of the information provided by the applicant, we have the following concerns regarding whether Lyfgenia™ meets the substantial clinical improvement criterion. With respect to the claim that Lyfgenia™ presents an acceptable risk-benefit profile in terms of efficacy and safety for patients with SCD while allowing clinically meaningful improvements in HRQoL, the applicant stated the safety profile remains generally consistent with risk of autologous stem cell transplant, myeloablative conditioning, and underlying SCD. Additionally, the applicant mentions that serious treatment-emergent adverse events (TEAEs) of grade 3 or higher TEAEs were reported, but no cases of veno-occlusive liver disease, graft failure, or vector-mediated replication competent lentivirus were reported. Per the applicant, three patients had adverse events attributed to Lyfgenia™, including 2 events deemed possibly related and 1 event deemed definitely related, with all 3 resolving within 1 week of onset. We note that the applicant submitted one published article about Group C results, an interim analysis by Kanter et al. (2022) [85] in which Lyfgenia™'s safety and efficacy were evaluated in a nonrandomized, open-label, single-dose phase 1–2 clinical trial (HGB–206) where 35 Group C patients had received Lyfgenia™ infusion. Group C was established after optimizing the treatment process in the initial cohorts, Groups A (7 patients) and B (2 patients). There was also a more stringent inclusion criterion for severe vaso-occlusive events before enrollment for Group C. The median follow-up was 17.3 months (range, 3.7–37.6) and 25 patients met both the inclusion criteria for vaso-occlusive events before enrollment and a minimum 6-month follow-up required for assessment of vaso-occlusive events. After receiving Lyfgenia™, 12 patients (34 percent) had at least one serious adverse event; the most frequently reported were abdominal pain, drug withdrawal syndrome (opiate), nausea, and vomiting (6 percent each). The two events that were deemed to be possibly related to Lyfgenia™ were grade 2 leukopenia and grade 1 decreased diastolic blood pressure and the one event that was deemed to be definitely related was grade 2 febrile neutropenia. Although this evidence was provided to assert Lyfgenia™ improves clinical outcomes relative to previously available therapies, we note that the risk-benefit profile and HRQoL for Lyfgenia™ is not compared to existing therapies. We would be interested in additional information regarding the risk-benefit profile of Lyfgenia™ compared to existing therapies, including clarification regarding an acceptable risk-benefit profile for patients with SCD and whether Lyfgenia™ fits this profile. We also question if the length of patient follow-up (median: 17.3 months, range: 3.7 to 37.6) would be sufficient to assess long-term safety outcomes.

Finally, with respect to the applicant's assertion that Lyfgenia™ improves clinical outcomes by halting SCD progression, presenting an acceptable risk-benefit profile with clinically meaningful improvement in HRQoL, and results in complete resolution of sVOEs, we note that the applicant provided multiple sources of evidence that analyze the same phase 1–2 clinical study for Lyfgenia™, HGB–206. We received an additional unpublished source [86] that provided some data on the phase 3 HGB–210 trial and combined this with data from HGB–206 with a total of 34 patients being evaluable for efficacy and 47 for safety. The median age of these 47 patients was 23 years. Due to the small study population and the median age of participants in the studies, we question if the safety and efficacy data from these studies would be generalizable to the Medicare population.

We are inviting public comments on whether Lyfgenia™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Lyfgenia™.

j. Quicktome Software Suite (Quicktome Neurological Visualization and Planning Tool)

Omniscient Neurotechnology submitted an application for new technology add-on payments for Quicktome Software Suite for FY 2025. According to the applicant, Quicktome Software Suite is a cloud-based software that uses artificial intelligence (AI) tools and the scientific field of connectomics to analyze millions of data points derived from a patient's magnetic resonance imaging (MRI). Per the applicant, Quicktome Software Suite's proprietary Structural Connectivity Atlas (SCA) uses machine learning and

[85] Kanter, J., Walters, M.C., Krishnamurti, L., Mapara, M.Y., Kwiatkowski, J.L, Rifkin-Zenenberg, S., Aygun, B., Kasow, K.A., Pierciey, Jr., F.J., Bonner, M., Miller, A., Zhang, X., Lynch, J., Kim, D., Ribeil, J.A., Asmal, M., Goyal, S., Thompson, A.A., & Tisdale, J.F. (2022). Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease. *The New England Journal of Medicine, 386,* 617–628. *https://doi.org/10.1056/nejmoa2117175.*

[86] Kanter J, et al. 65th ASH Annual Meeting and Exposition. December 9–12, 2023. Abstract 1051. Oral presentation (December 11th).

tractographic techniques to create highly specific and personalized maps of a patient's brain or connectome from a standard MRI scan, regardless of brain shape, size, or physical distortion. The applicant asserted that the SCA is combined with a key refinement algorithm which identifies the location of parcels based on the specific structural characteristics of an individual's brain. The applicant asserted that Quicktome Software Suite uses resting-state functional MRI (rs-fMRI) to unveil the brain's network architecture or functional connectome by mapping blood oxygen level dependent (BOLD) signal correlations across brain parcels. Per the applicant, using data from a structural or a functional MRI (fMRI) scan, Quicktome Software Suite's proprietary AI allows clinicians to quickly and accurately assess the structural layout (that is, the locations and integrity) or the functional connectivity (that is, how different brain regions are working together) of a patient's brain.

Please refer to the online application posting for Quicktome Software Suite, available at *https://mearis.cms.gov/public/publications/ntap/NTP23101722NQE,* for additional detail describing the technology and the disease for which the technology is used.

With respect to the newness criterion, according to the applicant, the Quicktome Software Suite received FDA 510(k) clearance on May 30, 2023. Per the FDA-cleared indication, the Quicktome Software Suite is composed of a set of modules intended for the display of medical images and other healthcare data. It includes functions for image review, image manipulation, basic measurements, planning, 3D visualization (MPR reconstructions and 3D volume rendering), and the display of BOLD rs-MRI scan studies. The FDA clearance for Quicktome Software Suite was based on substantial equivalence to the legally marketed predicate device, StealthViz Advanced Planning Application with Stealth Diffusion Tensor Imaging (DTI)™ Package (hereafter referred to as StealthViz™), as both of these devices allow the import and export of DICOM images to a hospital picture archiving and communication system (PACS); contain a graphical user interface to conduct planning and visualization; display MRI anatomical images, as well as tractography constructed from Diffusion Weighted Images, in 2D and 3D views; register tractography and an atlas to the underlying anatomical images; allow adding, removing, and editing of objects (including automatically segmented and manually defined regions of interest); and are delivered as software on an off-the-shelf hardware platform.[87] Prior to the FDA 510(k) clearance of Quicktome Software Suite™ in 2023, the technology, under the trade name Quicktome, received FDA 510(k) clearance on March 9, 2021, based on substantial equivalence to StealthViz™.[88] StealthViz™ received FDA 510(k) clearance on May 16, 2008 for use in two- and three-dimensional (2D and 3D) surgical planning and image review and analysis. According to the FDA 510(k) summary for StealthViz™, it enables digital diagnostic and functional imaging datasets, reviewing and analyzing the data in various 2D and 3D presentation formats, performing image fusion of datasets, segmenting structures in the images with manual and automatic tools and converting them into 3D objects for display, and exporting results to other Medtronic Navigation planning applications, to a PACS or to Medtronic Navigation surgical navigation systems such as StealthStation System. According to the applicant, the Quicktome Software Suite was commercially available immediately after FDA clearance.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Quicktome Software Suite. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Quicktome Software Suite beginning in FY 2025. The applicant provided a list of diagnosis codes that may currently be used to identify the indication for Quicktome Software Suite under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered new for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Quicktome Software Suite is not substantially similar to other currently available technologies because it is the first and only FDA-cleared platform to enable connectomic analysis at an individual level using machine learning and tractographic techniques to create personalized maps of the human brain. In addition, the applicant asserted that Quicktome Software Suite is the first cleared neurological planning tool to offer rs-fMRI capabilities. Per the applicant, Quicktome Software Suite eliminates the need for highly trained personnel, who may not be available at most institutions, and therefore, the technology meets the newness criterion. The applicant further asserted that current technologies that rely on task-based fMRI (tb-fMRI) can be problematic in brain tumor patients who may be cognitively impaired because they may be unable to perform required tasks. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Quicktome Software Suite for the applicant's complete statements in support of its assertion that the Quicktome Software Suite is not substantially similar to other currently available technologies.

[87] Food and Drug Administration (FDA). 510(k) Premarket notification for Medtronic Navigation, Inc.'s StealthViz Advanced Planning Application with StealthDTI Package. K081512. May 16, 2008.

[88] FDA. K203518. 2021.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	The applicant noted that while Quicktome Software Suite is not therapeutic in nature, it is unique in its mechanism of action. Per the applicant, Quicktome Software Suite is the first and only FDA-cleared platform to enable connectomic analysis at an individual level. The applicant stated that the technology's proprietary SCA, a newly developed brain mapping technique, uses machine learning and tractographic techniques to create personalized maps of the human brain, providing clinicians with unprecedented information about the location and function of a patient's brain networks, which was previously only available in research settings.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	The applicant maintained that the technology provides critical supplementary information for patients admitted under existing DRGs for procedures and conditions such as craniotomy.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	Per the applicant, Quicktome Software Suite does not treat a new disease type or patient population but does provide new information for the treatment of existing patient populations.

We note the following concerns regarding whether Quicktome Software Suite meets the newness criterion. With respect to the applicant's claim that Quicktome Software Suite does not use the same or similar mechanism of action as existing technologies to achieve a therapeutic outcome, we note that, according to the 510(k) application, it appears that the Quicktome Software Suite is equivalent to StealthViz™, its predicate device. We are unclear how the Quicktome Software Suite's mechanism of action, which enables patient-specific connectomic analysis for neurological planning, is different from that of StealthViz™. We note that StealthViz™ received FDA 510(k) clearance on May 16, 2008 for use in 2D/3D surgical planning and image review and analysis, and therefore is no longer considered new for purposes of new technology add-on payments. According to the applicant, Quicktome Software Suite is the first and only FDA-cleared platform to enable brain network mapping and analysis at an individual level and provides clinicians with information that was previously only available in a research setting. We would be interested in further information to support that the Quicktome Software Suite does not use the same or similar mechanism of action as StealthViz™ to achieve a therapeutic outcome, including information regarding capabilities of Quicktome Software Suite not found in StealthViz™, and whether and how those capabilities are the result of a new mechanism of action.

In addition, we note that there are several existing FDA-approved or cleared technologies (for example, StealthViz™, Brainlab's Elements and iPlan products) that analyze fMRI and other medical imaging data to create 3-D maps of a patient's brain, including white matter tracts. Furthermore, while the applicant asserted that Quicktome Software Suite is the only FDA-cleared device that uses a rs-fMRI, we question whether other FDA-cleared neurosurgical planning and visualization technologies integrate rs-fMRI, or if the analysis of rs-fMRI for neurosurgical planning is a mechanism of action unique to Quicktome Software Suite. We would be interested in more information on the relevant current standard of care and technologies utilized for neurosurgical planning and how the mechanism of action of the Quicktome Software Suite compares to the mechanism of action of existing technologies and connectomics software.

With respect to the third criterion, whether Quicktome Software Suite involves the treatment of the same or similar disease and patient population compared to existing technologies, we note that the applicant stated that the Quicktome Software Suite does not treat a new disease type or patient population, but does provide new information for the treatment of existing patient populations. However, the provision of new information for the treatment of existing patient populations does not mean that the technology treats a new disease type or patient population, and therefore, it is unclear what the basis is for the applicant's statement that the third criterion is not met. We would be interested in additional information to support whether and how Quicktome Software Suite may involve the treatment of a different type of disease or patient population.

As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44981), we also continue to be interested in public comments regarding issues related to determining newness for technologies that use AI, an algorithm, or software. Specifically, we are interested in public comment on how these technologies may be considered for the purpose of identifying a unique mechanism of action; how updates to AI, an algorithm, or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology.

We are inviting public comments on whether Quicktome Software Suite is substantially similar to existing technologies and whether Quicktome Software Suite meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for Quicktome Software Suite, the applicant searched 2020 Medicare Inpatient

Hospitals—by Provider and Service data.[89] The applicant included all cases from the following MS–DRGs: 025 (Craniotomy and Endovascular Intracranial Procedures with MCC), 026 (Craniotomy and Endovascular Intracranial Procedures with CC), and 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC). Using the inclusion/exclusion criteria described in the following table, the applicant identified 28,401 cases mapping to these three craniotomy MS–DRGs, with 64 percent of the identified cases mapping to MS–DRG 025. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $179,317, which exceeded the average case-weighted threshold amount of $134,802. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that Quicktome Software Suite meets the cost criterion.

QUICKTOME SOFTWARE SUITE COST ANALYSIS	
Data Source and Time Period	2020 Medicare Inpatient Hospitals – by Provider and Service data
List of MS-DRGs	DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC) DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC) DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC)
Inclusion/exclusion criteria	The applicant asserted that Quicktome is relevant to all procedure and diagnosis codes which may lead to a craniotomy procedure, therefore it included all cases assigned to the listed MS-DRGs and applied no restrictions regarding ICD-10-CM/PCS codes as it indicated that all stays related to the MS-DRGs listed previously are relevant.
Charges removed for prior technology	The applicant stated that it did not remove indirect charges related to the prior technology because Quicktome Software Suite would not replace prior technologies. Per the applicant, Quicktome Software Suite would supplement existing MRIs to provide detail regarding brain structural and functional analysis to improve patient outcomes.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 32% to the standardized charges, as a five-year inflation factor calculated based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added the cost for the Quicktome Software Suite but did not convert the previously noted costs to charges for the new technology. In addition, the applicant estimated indirect costs related to the technology. Per the applicant, it took into account the operating costs related to an additional 18-minute scan time compared to the typical MRI scan. The applicant also added costs of additional capital MRI equipment needed to produce the MRI scans for Quicktome Software Suite. Specifically, per the applicant, MRI hardware and infrastructure must, at minimum, include scanners equipped with DTI capabilities. The applicant noted that while it assumed only DTI capabilities as a baseline additional expense, the actual hardware and infrastructure costs for most hospitals are likely much higher. The applicant did not convert the indirect costs to charges for the new technology.

We note the following concerns regarding the cost criterion. We note that the applicant limited its cost analysis to MS–DRGs 025, 026, and 027 because those three MS–DRGs represent brain tumor resection procedures, which are the first and most clearly established procedures for which the technology offers clinical utility. We are interested in information as to whether the technology would map to other MS–DRGs, such as 023 and 024 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy, or without MCC, respectively), or 054 and 055 (Nervous System Neoplasms with and without MCC, respectively), and if these MS–DRGs should also be included in the cost analysis. In addition, we question whether every case within MS–DRGs 025, 026, 027 would be eligible for the technology and whether there would be any appropriate inclusion/exclusion criteria by ICD–10–CM/PCS codes within these MS–DRGs to identify potential cases representing patients who may be eligible for Quicktome Software Suite.

We are inviting public comments on whether Quicktome Software Suite meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Quicktome Software Suite represents a substantial clinical improvement over existing technologies because Quicktome supports the visualization and brain mapping that improve clinical outcomes such as reducing the risk of an extended length of stay (LOS) and unplanned readmissions for craniotomy patients by reducing new postoperative neurological deficits that are caused by damage to brain networks or a patient's connectome. The applicant further asserted that Quicktome Software Suite is the first and only FDA-cleared platform to enable connectomic analysis at an individual level, enabling surgeons to visualize and avoid damaging these brain networks during surgery, thereby significantly improving clinical

[89] The Medicare Inpatient Hospitals by Provider and Service dataset provides information on inpatient discharges for Original Medicare Part A beneficiaries by IPPS hospitals. It includes information on the use, payment, and hospital charges for more than 3,000 U.S. hospitals that received IPPS payments. The data are organized by hospital and Medicare Severity Diagnosis Related Group (DRG): *https://data.cms.gov/provider-summary-by-type-of-service/medicare-inpatient-hospitals/medicare-inpatient-hospitals-by-provider-and-service.*

outcomes relative to services or technologies previously available. The applicant submitted three published studies and one unpublished study evaluating the Quicktome Software Suite to support these claims, as well as four background articles about complications leading to unplanned readmissions after cranial surgery, factors associated with extended LOS in patients undergoing craniotomy for tumor resection, the association of incorporating fMRI in presurgical planning with mortality and morbidity in brain tumor patients, and the clinical importance of non-traditional, large-scale brain networks with respect to the potential adverse effects on patients when these networks are disrupted during surgery.[90] We note that one of the articles submitted as a study using the technology, the Dadario and Sughrue (2022)[91] study, should more appropriately be characterized as a background article because it does not directly assess the use of Quicktome Software Suite.

The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Quicktome Software Suite for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Quicktome Software Suite supports the visualization of brain networks and surgical planning to avoid damaging them during surgery	Shah HA, Ablyazova F, Alrez A, et al. Intraoperative awake language mapping correlates to preoperative connectomics imaging: An instructive case. *Clin Neurol Neurosurg.* 2023 Jun;229:107751. Doi: 10.1016/j.clineuro.2023.107751. Epub 2023 Apr 29. PMID: 3714997. 2. Wu Z, Hu G, Cao B, Liu X, et al. Non-traditional cognitive brain network involvement in insulo-Sylvian gliomas: a case series study and clinical experience using Quicktome. *Chin Neurosurg J.* 2023 May 26;9(1):16. Doi: 10.1186/s41016-023-00325-4 PMID: 37231522; PMCID: PMC10214670. Morell AA, Eichberg DG, Shah AH, et al. Using machine learning to evaluate large-scale brain networks in patients with brain tumors: Traditional and non-traditional eloquent areas. *Neurooncol Adv.* 2022 Sep 19;4(1):vdac142. Doi: 10.1093/noajnl/vdac142 PMID: 36299797; PMCID: PMC9586213. Hendricks B, Scherschinkski L, Jubran J, et al. Supratentorial Cavernous Malformation Surgery: The Seven Hotspots of Novel Cerebral Risk (SUBMITTED MANUSCRIPT).
Damaging brain networks during surgery leads to neurologic complications, which are a leading contributor to increased length of stay, ICU admission, and readmissions	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Damaging brain networks during surgery has adverse effects for patients, including decreased quality of life and loss of function.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.

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After our review of the information provided by the applicant, we have the following concerns regarding whether Quicktome Software Suite meets the substantial clinical improvement criterion.

With respect to the applicant's claim that Quicktome Software Suite supports the visualization of brain networks and surgical planning to avoid damaging them during surgery, we are concerned that the evidence does not appear to demonstrate that the Quicktome Software Suite's visualization and brain mapping techniques improve clinical outcomes relative to services or technologies already available by avoiding or reducing damage to the brain networks during surgery. For example, the Shah et al. (2023)[92] study

[90] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[91] Dadario NB, Sughrue ME. Should Neurosurgeons Try to Preserve Non-Traditional Brain Networks? A Systematic Review of the Neuroscientific Evidence. *Journal of Personalized Medicine.* 2022; 12(4):587. *https://doi.org/10.3390/jpm12040587.*

[92] Shah HA, Ablyazova F, Alrez A, et al. Intraoperative awake language mapping correlates to preoperative connectomics imaging: An instructive case. *Clin Neurol Neurosurg.* 2023 Jun;229:107751. Doi: 10.1016/j.clineuro.2023.107751 Epub 2023 Apr 29. PMID: 3714997. 2.

describes the use of connectomics in planning and guiding an awake craniotomy for a tumor impinging on the language area in a 31-year-old bilingual woman. The authors stated that Quicktome Software Suite was used to generate preoperative connectome imaging for the patient, which helped in assessing the risk of functional deficits, guiding surgical planning, directing intraoperative mapping stimulation, and providing insights into postoperative function. The authors further described how preoperative imaging demonstrated proximity of the tumor to parcellations of the language area, and how intraoperative awake language mapping was performed, revealing speech arrest and paraphasic errors at areas of the tumor boundary correlating to functional regions that explained these findings. However, we are concerned that the report is based on a single case, and we question whether these findings would be generalizable to the broader Medicare population. In addition, we note that the applicant did not provide evidence based on comparison of the use of Quicktome Software Suite technology with currently available cranial mapping software or tractography tools, and we would be interested in comparisons that assess the use of Quicktome Software Suite technology to improve these clinical outcomes relative to currently available technologies, such as StealthViz™ or Brainlab's Elements and iPlan products.

In addition, we question whether the findings related to Quicktome's efficacy are generalizable to the Medicare population. Specifically, the Wu et al. (2023) [93] study aimed to investigate the involvement of non-traditional brain networks in insulo-Sylvian gliomas and evaluate the potential of Quicktome Software Suite in optimizing surgical approaches to preserve cognitive function. The study included three parts. The first part involved a retrospective analysis of the location of insulo-Sylvian gliomas in 45 adult patients who underwent glioma surgery centered in the insular lobe. According to the research team, Quicktome showed that 98 percent of the tumors involved a non-traditional eloquent brain network, which is associated with cognitive or neurological function. In part two, the research team prospectively collected neuropsychological data on seven patients to assess tumor-network involvement with change in cognition. Using Quicktome, the research team found that all seven patients had a tumor involving a non-traditional eloquent brain network. Part three described how the research team used Quicktome Software Suite's network mapping capabilities to inform surgical decision-making and predict the preservation of cognitive function post-surgery for two prospective patients. We note that while Quicktome Software Suite was used to assist surgical decision-making in two patients, as previously discussed, we question whether these limited findings would be generalizable to the broader Medicare population, and we would be interested in comparisons between Quicktome Software Suite and other currently available technologies to improve these clinical outcomes.

We also question whether the use of Quicktome Software Suite has a direct impact on significantly reducing neurological or cognitive deficits post-surgery. The applicant cited Morell et al. (2022),[94] a retrospective, single-center study of 100 patients who underwent surgery for brain tumor resection. The research team used Quicktome Software Suite to map and evaluate the integrity of nine large-scale brain networks in these patients. According to the research team, Quicktome's analysis showed that for more than half of these patients, at least one of their brain networks were either affected during brain surgery or at risk of postsurgical deficits. Among those at risk of postsurgical deficits, their cortical regions or white matter fibers were either displaced by the mass effect of the tumor or damaged during surgery due to proximity to the tumor and/or planned transcortical trajectory. We note that the primary focus of the study was to retrospectively map large-scale brain networks in brain tumor patients using Quicktome Software Suite platform, and therefore does not appear to demonstrate that use of Quicktome Software Suite avoided damaging these networks during surgery.

Similarly, we note that the applicant cited Hendricks et al. (n.d.),[95] which retrospectively analyzed the outcomes of 346 adult patients who underwent resection of superficial cerebral cavernous malformations (CMs) from November 2008 through June 2021. We note that the focus of the study was the use of Quicktome Software Suite to support the identification of areas of eloquent noneloquence, or cortex injured or transgressed that causes unexpected deficits. Therefore, we remain interested in evidence that incorporating Quicktome Software Suite's analytics into surgical strategies and navigational tools during craniotomy surgery is associated with improved post-surgical outcomes.

With respect to the applicant's claim that damaging brain networks during surgery leads to neurologic complications, which are a leading contributor to increased length of stay (LOS), ICU admission, and readmissions, the applicant asserted that Quicktome Software Suite enables surgeons to visualize these brain networks and change their surgical approach as needed to avoid damaging these networks. We note that the applicant submitted two documents in support of this claim, both of which are background documents rather than studies that evaluate clinical outcomes associated with the use of Quicktome Software Suite. In particular, the Elsamadicy et al. (2018) [96] study showed that altered mental status and sensory or motor deficits were the primary complications of craniotomies. The Philips et al. (2023) [97] study demonstrated that post-operative neurological deficits, caused by damage to brain networks or a patient's connectome were responsible for extended length of stay. Although these studies supported the applicant's claim that damage to brain networks resulted in neurological complications, increasing LOS and inpatient service use, we note that the evidence provided for this claim does not assess the use of Quicktome Software Suite to improve these clinical outcomes, nor does the evidence appear to demonstrate that use of the technology substantially improves these clinical outcomes relative to existing technologies, such as StealthViz™ or Brainlab's Elements and iPlan products. We would be interested in evidence demonstrating that

[93] Wu Z, Hu G, Cao B, Liu X, et al. Non-traditional cognitive brain network involvement in insulo-Sylvian gliomas: a case series study and clinical experience using Quicktome. *Chin Neurosurg J.* 2023 May 26;9(1):16. Doi: 10.1186/s41016–023–00325–4 PMID: 37231522; PMCID: PMC10214670.

[94] Morell AA, Eichberg DG, Shah AH, et al. Using machine learning to evaluate large-scale brain networks in patients with brain tumors: Traditional and non-traditional eloquent areas. *Neurooncol Adv.* 2022 Sep 19;4(1):vdac142. Doi: 10.1093/noajnl/vdac142. PMID: 36299797; PMCID: PMC9586213.

[95] Hendricks B, Scherschinkski L, Jubran J, et al. Supratentorial Cavernous Malformation Surgery: The Seven Hotspots of Novel Cerebral Risk (SUBMITTED MANUSCRIPT).

[96] Elsamadicy, AA, Sergesketter, A, Adogwa, O, et al. Complications and 30-Day readmission rates after craniotomy/craniectomy: A single Institutional study of 243 consecutive patients, *Journal of Clinical Neuroscience,* Volume 47, 2018, Pages 178–182, ISSN 0967–5868, *https://doi.org/10.1016/j.jocn.2017.09.021.*

[97] Phillips KR, Enriquez-Marulanda A, Mackel C, et al. Predictors of extended length of stay related to craniotomy for tumor resection. *World Neurosurg* X. 2023 Mar 31;19:100176. doi:10.1016/j.wnsx.2023.100176 PMID: 37123627; PMCID: PMC10139985.

utilization of the Quicktome Software Suite improves clinical outcomes related to LOS, ICU admissions, and readmissions relative to existing technologies.

With respect to the applicant's claim that damaging brain networks during surgery has adverse effects for patients, including decreased quality of life and loss of function, the applicant asserted that Quicktome Software Suite enables surgeons to visualize brain networks and change their surgical approach as needed to avoid damaging these networks. The applicant further asserted that while other techniques have enabled the visualization of tractography or of parts of eloquent networks, this is not an adequate substitute for the ability to review the entirety of a patient's connectome (networks such as motor, language, and vision). Per the applicant, Quicktome Software Suite is the first of its kind to show the location and function of these networks and that damage to these networks is associated with poor outcomes. The applicant cited Vysotski et al. (2019),[98] who demonstrated that brain tumor patients who underwent a preoperative fMRI experienced significantly lower risks for mortality than those who did not. The applicant also cited Dadario and Sughrue (2022),[99] who discussed the clinical importance of preserving non-traditional brain networks for neurosurgical patients. Similar to our previous concern, we note that the evidence provided for this claim does not assess the use of Quicktome Software Suite to improve quality of life and loss of function, nor does the evidence appear to demonstrate that use of the technology substantially improves these clinical outcomes relative to existing technologies. Therefore, we continue to question whether there is evidence to assess the effectiveness of Quicktome Software Suite to reduce damage to brain networks during surgery.

We are also interested in public comments related to how we should evaluate issues related to determining substantial clinical improvement for technologies that use AI, an algorithm or software, including issues related to algorithm transparency, and how CMS should consider these issues in our assessment of substantial clinical improvement, as we continue to gain experience in this area. Algorithm transparency refers to whether, and the extent to which, clinical users are able to access a consistent, baseline set of information about the algorithms they use to support their decision making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.[100]

We are inviting public comments on whether Quicktome Software Suite Software Suite meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Quicktome Software Suite.

k. TALVEY™ (talquetamab-tgvs)

Johnson & Johnson Health Care Systems, Inc. submitted an application for new technology add-on payments for TALVEY™ for FY 2025. According to the applicant, TALVEY™ is the first and only approved G protein-coupled receptor, class C, group 5, member D (GPRC5D) targeting therapy, a bispecific antibody (bsAb) approved for the treatment of adults with Relapsed or Refractory Multiple Myeloma (RRMM) who have received at least four prior lines of therapy (also referred to herein as 4L+RRMM), including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-cluster of differentiation (CD)38 monoclonal antibody (mAb). GPRC5D is an orphan receptor expressed at a significantly higher level on malignant Multiple Myeloma (MM) cells than on normal plasma cells.

Please refer to the online application posting for TALVEY™ available at *https://mearis.cms.gov/public/publications/ntap/NTP2310163HW2V,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, TALVEY™ was granted a Biologic License from FDA on August 9, 2023 for the treatment of adult patients with 4L+RRMM who have received at least four prior lines of therapy, including a PI, an ImiD, and an anti-CD38 mAb. According to the applicant, TALVEY™ was commercially available immediately after FDA approval. Per the applicant, patients may be dosed on a weekly or bi-weekly dosing schedule. The applicant noted that patients on a weekly dosing schedule receive three weight-based doses—a 0.01 mg/kg loading dose, a 0.06 mg/kg loading dose, and the first 0.40 mg/kg treatment dose—during the hospital stay; patients on a bi-weekly dosing schedule receive an additional 0.80 mg/kg treatment dose during the hospital stay.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for TALVEY™ and was granted approval for the following procedure code effective April 1, 2024: XW01329 (Introduction of talquetamab antineoplastic into subcutaneous tissue, percutaneous approach, new technology group 9). The applicant stated that ICD–10–CM codes C90.00 (Multiple myeloma not having achieved remission) and C90.02 (Multiple myeloma in relapse) may be used to currently identify the indication for TALVEY™.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that TALVEY™ is not substantially similar to other currently available technologies because it has a unique mechanism of action as a CD3 T-cell engaging bsAb targeting GPRC5D, and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for TALVEY™ for the applicant's complete statements in support of its assertion that TALVEY™ is not substantially similar to other currently available technologies.

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[98] Vysotski S, Madura C, Swan B, et al. Preoperative FMRI Associated with Decreased Mortality and Morbidity in Brain Tumor Patients. Interdiscip Neurosurg. 2018 Sep;13:40–45. doi: 10.1016/j.inat.2018.02.001 Epub 2018 Feb 14. PMID: 31341789; PMCID: PMC6653633.

[99] Dadario NB, Sughrue ME. Should Neurosurgeons Try to Preserve Non-Traditional Brain Networks? A Systematic Review of the Neuroscientific Evidence. *Journal of Personalized Medicine.* 2022; 12(4):587. *https://doi.org/10.3390/jpm12040587.*

[100] Department of Health and Human Services (December 13, 2023). HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency | *HHS.gov,* accessed 2/20/2024.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	TALVEY™ has a unique mechanism of action as the first and only approved therapy targeting GPRC5D. TALVEY™ is a full-sized, bsAb that simultaneously binds GPRC5D on myeloma cells and CD3 on T-cells. This distinction is critical, because the expression of GRPC5D is different from that of BCMA, which is the target of the other approved bsAbs in RRMM. Of note, GPRC5D has limited expression on normal tissues, including the tongue and hair follicles. Critically, GPRC5D is not expressed at a significant level on normal B-cells, which directly contrasts with BCMA expression which is present on B-cells. The tissue expression of GPRC5D determines, in large part, the AE profile of TALVEY™ and differentiates the mechanism of action and AE profile of TALVEY™ from those of BCMA targeting therapies. Other FDA approved T-cell engaging bsAbs include teclistamab, elranatamab (MM), mosunetuzumab, epcoritamab, glofitamab (B-cell non-Hodgkin lymphoma), and blinatumomab (acute lymphoblastic leukemia). While teclistamab and elranatamab are also T-cell engaging bsAbs used to treat multiple myeloma, they both target BCMA. TALVEY™ is the only medicine which targets the novel antigen GPRC5D. Mosunetuzumab, epcoritamab, and glofitamab target CD3 on T-cells and CD20 on non-Hodgkin lymphoma cells and are approved for use in relapsed/refractory B-cell non-Hodgkin lymphoma. Blinatumomab, a bispecific T-cell engager (BiTE) that targets CD3 and CD19, is approved for the treatment of pre-B-cell acute lymphoblastic lymphoma and has a structure different from other bsAbs, containing two Fab fragments that are held together by a chemical linker. TALVEY™ has a novel mechanism of action targeting GPRC5D for the treatment of MM and is differentiated from existing bsAbs due to the uniqueness of both this target and its tissue expression profile, which results in an adverse event profile distinct from those of the currently approved bsAbs in RRMM targeting BCMA.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	TALVEY has been assigned to the same MS-DRG and it treats a similar MM patient population as several other approved therapies.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	TALVEY™ is indicated for the treatment of adults with 4L+RRMM, including a PI, an IMiD and an anti-CD38 mAb. The indication for TALVEY™ is similar to the approved indications for ide-cel, cilta-cel, teclistamab, and elranatamab. While these are all BCMA targeted therapies indicated for the treatment of MM in patients who have been exposed to at least four prior lines of therapy, TALVEY™ is unique in that it targets the novel antigen GPRC5D. In addition, TALVEY™ has proven efficacy in patients with RRMM who have received prior T-cell redirection therapies such as BCMA-directed Chimeric antigen receptor (CAR) T-cell therapy and bsAbs.

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With regard to the newness criterion, we note that TALVEY™ may have a similar mechanism of action to that of TECVAYLI®, for which we approved an application for new technology add-on payments for FY 2024 for the treatment of adult patients with RRMM after four or more prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb (88 FR 58891). We also note that TALVEY™ may have a similar mechanism of action to that of ELREXFIO™, another applicant for FY 2025 new technology add-on payments. As previously discussed, ELREXFIO™ was approved on August 14, 2023 for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb.

Per the applicant, TALVEY™ has a different mechanism of action from TECVAYLI® or ELREXFIO™ because it binds to different receptors. The applicant noted that TALVEY™ is the only medicine that targets GPRC5D on myeloma cells. As we previously noted, TECVAYLI®'s mechanism of action is described as a bsAb, with binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor (88 FR 58886). As previously discussed, the mechanism of action for ELREXFIO™ is as a bsAb that uses binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor. However, while the applicant asserts that TALVEY™ has a unique mechanism of action as compared to TECVAYLI® and ELREXFIO™ by binding to different receptors, we question how binding to a different protein (GPRC5D) on the tumor cell would result in a different mechanism of action compared to BCMA targeting bispecific antibodies. Furthermore, we note that the applicant claimed that the target of TALVEY™, GPRC5D, has a unique tissue expression profile, which results in an adverse event profile distinct from those of the currently approved bispecific antibodies in RRMM targeting BCMA. However, as this relates to the risk of adverse event from TALVEY™ administration but is not critical to the way the drug treats the underlying disease, we question whether this would therefore relate to an assessment of substantial clinical

improvement rather than of substantial similarity. We would welcome additional information on how molecular differences, such as the regulation of expression of GPRC5D and BCMA on MM cells during treatment, should be considered in determining whether a technology utilizes a different mechanism of action to achieve a therapeutic outcome.

Accordingly, as it appears that TALVEY™ and TECVAYLI® may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if we determine that this technology is substantially similar to TECVAYLI®, we believe the newness period would begin on November 9, 2022, the date TECVAYLI™ became commercially available (88 FR 58887).

Furthermore, as noted, we believe another applicant for FY 2025 new technology add-on payments, ELREXFIO™, may also be substantially similar to TALVEY™. Per the application for ELREXFIO™, ELREXFIO™ is a bispecific antibody approved for the treatment of adults with RRMM who have received at least four prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb. We believe ELREXFIO™ may be substantially similar to TALVEY™ because it is also a bispecific antibody that treats RRMM in patients who have previously received a PI, IMiD, and an anti-CD38 mAb. Additionally, we note that similar to TALVEY™, the prescribing information for ELREXFIO™ includes the population with prior exposure to BCMA T-cell redirection therapy. Accordingly, as it appears that TALVEY™ and ELREXFIO™ would use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and would treat the same or similar patient population and disease, we believe that these technologies may also be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We note that if TALVEY™ is determined to only be substantially similar to ELREXFIO™, and not TECVAYLI®, we believe the newness period for TALVEY™ would begin on August 9, 2023, the date TALVEY™ received FDA approval.

We are interested in receiving information on how these technologies may differ from each other with respect to the substantial similarity and newness criteria, to inform our analysis of whether TALVEY™ is substantially similar to ELREXFIO™ and/or TECVAYLI®.

We are inviting public comments on whether TALVEY™ is substantially similar to existing technologies and whether TALVEY™ meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for TALVEY™, the applicant searched the FY 2022 MedPAR for cases reporting one of the following ICD–10–CM codes in the first five diagnosis positions on the claim: C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), and C90.02 (Multiple myeloma in relapse). Using the inclusion/exclusion criteria described in the following table, the applicant identified 4,468 claims mapping to five MS–DRGs with 82 percent of identified cases mapping to MS–DRGs 840 and 841 (Lymphoma and Non-acute Leukemia with MCC, with CC, respectively). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $210,677, which exceeded the average case-weighted threshold amount of $77,360. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that TALVEY™ meets the cost criterion.

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TALVEY™ COST ANALYSIS	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	C90.00 (Multiple myeloma not having achieved remission) C90.01 (Multiple myeloma in remission) C90.02 (Multiple myeloma in relapse)
List of ICD-10-PCS codes	3E01305 (Introduction of other antineoplastic into subcutaneous tissue, percutaneous approach)
List of MS-DRGs	840 (Lymphoma and Non-acute Leukemia with MCC) 841 (Lymphoma and Non-acute Leukemia with CC) 842 (Lymphoma and Non-acute Leukemia without CC/MCC) 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC)
Inclusion/exclusion criteria	The applicant identified cases by using the ICD-10-CM codes in this table in the first five diagnosis positions. The applicant limited the analysis to the following six identified MS-DRGs that involved the treatment of multiple myeloma: MS-DRGs 840, 841, 842 (Lymphoma and Non-acute Leukemia with MCC, with CC, without CC/MCC, respectively), and MS-DRGs 846, 847, 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC, with CC, without CC/MCC, respectively). The applicant stated that although MS-DRG 848 was identified as a MS-DRG that should be included in the analysis, no claims with an appropriate multiple myeloma diagnosis code were identified in this MS-DRG.
Charges removed for prior technology	Per the applicant, for some patients, use of TALVEY™ could replace other drug therapies during the inpatient stay. The applicant stated since it is difficult to identify the exact differences in drug regimens TALVEY™ patients would receive, it removed 100% of drug charges from the identified cases as a conservative approach. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.9% to the standardized charges, based on the two-year inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether TALVEY™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that TALVEY™ represents a substantial clinical improvement over existing technologies because TALVEY™ meets two of three criteria for substantial clinical improvement due to its off-the-shelf availability without the need for complex manufacturing. Additionally, according to the applicant, TALVEY™ demonstrates clinically meaningful outcomes in heavily pre-treated patients who are exposed or naive to prior T-cell redirection therapy and provides a therapeutic option with a lower severe infection rate. The applicant provided four studies to support these claims. We also note that four other articles submitted as supporting evidence should more appropriately be characterized as background articles because they do not directly assess the use of TALVEY™. Instead, those four articles focus on existing treatment options (ELREXFIO™ or TECVAYLI®) or the high mortality rate of MM patients who died while waiting for CAR–T cell therapies.[101]

The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for TALVEY™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[101] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
TALVEY™ offers an efficacious treatment option for patients that are unable to receive CAR T-cell therapy	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
TALVEY™ has a low incidence of serious and higher-grade infections, and preserves B-cell function	Hammons L, Szabo, A, Janardan, A, et al. The changing spectrum of infection with BCMA and GPRC5D targeting bispecific antibody (bsAb) therapy in patients with relapsed refractory multiple myeloma. *Haematologica*. 2023 Aug 31. Rodriguez-Otero, P, Schinke, C, Chari, A, et al. Analysis of infections and parameters of humoral immunity in patients with relapsed/refractory multiple myeloma treated with Talquetamab monotherapy in MonumenTAL-1. 2023 American Society of Clinical Oncology Annual Meeting, Poster #8020.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
TALVEY™ offers clinically meaningful outcomes in heavily pre-treated patients naïve to prior bispecific antibody and CAR-T cell therapy	Schinke, CD, Touzeau, C, Minnema, MC, et al. Pivotal Phase 2 MonumenTAL-1 results of Talquetamab, a GPRC5DxCD3 bispecific antibody, for relapsed/refractory multiple myeloma. 2023 American Society of Clinical Oncology Annual Meeting, Poster #8036. Jakubowiak, AJ, Anguille, S, Karlin, L, et al. Updated Results of Talquetamab, a GPRC5D×CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma with prior exposure to T-Cell redirecting therapies: results of the Phase 1/2 MonumenTAL-1 Study 2023 American Society of Hematology Annual Meeting. Poster #3377.
TALVEY™ offers clinically meaningful outcomes in patients exposed to prior bispecific antibody and CAR-T cell therapy	Schinke (2023), *op.cit.* Jakubowiak (2023). *op.cit.*

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After review of the information provided by the applicant, we have the following concerns regarding whether TALVEY™ meets the substantial clinical improvement criterion. With respect to the applicant's claim that TALVEY™ offers an efficacious treatment option for patients who are unable to receive CAR T-cell therapy, we note that TECVAYLI® and ELREXFIO™ are recently FDA-approved alternatives to CAR T-cell therapy with the same indication as treatments for RRMM for patients ineligible or unresponsive to four prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb. In addition, although the applicant claimed that TALVEY™ is more accessible than CAR T-cell therapies because it is readily available and can be delivered at any acute care hospitals, we would be interested in evidence comparing the effects of TALVEY™ and CAR T-cell therapies on mortality and other clinical outcomes, as we did not receive results from clinical trials comparing the efficacy of TALVEY™ with CAR T-cell therapies.

With respect to the applicant's claim that TALVEY™ has a low incidence of serious and higher-grade infections and preserves B-cell function, we note that the clinical data from the Hammons et al. (2023) [102] study did not appear to support this claim. Specifically, the difference in the proportion of grade 3+ infections among patients treated with BCMA bsAb (58 percent), GPRC5D bsAb combination therapy with daratumumab and/or pomalidomide (33 percent), and GPRC5D bsAb monotherapy (50 percent) was not statistically significant (p = 0.06). While the total infection rate per 100 days was lower for the GPRC5D monotherapy group, the difference was not statistically significant (BCMA: 0.57 percent, GPRC5D combination: 0.62 percent, GPRC5D monotherapy: 0.13 percent; p = 0.06). Moreover, the differences among the three groups in bacterial, viral, and fungal infection rates per 100 days did not reach statistical significance (p = 0.07, 0.4, and 0.14 respectively). In addition, the difference among the three groups regarding the need for hospitalization was not statistically significant (p = 0.07). Similarly, we note that according to the Rodriguez-Otero et al. (2023) [103] poster presentation, of the 339 patients treated with TALVEY™, 64 percent (n = 217) experienced infections, of which 29 percent (n = 63) experienced grade 3–4 infections. The applicant highlighted a conclusion in the Rodriguez-Otero poster that infection

[102] Hammons L, Szabo, A, Janardan, A, et al. The changing spectrum of infection with BCMA and GPRC5D targeting bispecific antibody (bsAb) therapy in patients with relapsed refractory multiple myeloma. *Haematologica*. 2023 Aug 31.

[103] Rodriguez-Otero, P, Schinke, C, Chari, A, et al. Analysis of infections and parameters of humoral immunity in patients with relapsed/refractory multiple myeloma treated with Talquetamab monotherapy in MonumenTAL–1. 2023 American Society of Clinical Oncology Annual Meeting, Poster #8020.

rates, particularly rates of higher grade and fatal infections, occurred less frequently with TALVEY™ compared with those observed in BCMA-targeted T-cell based therapies. We note that because clinical trials are conducted under widely varying conditions, we question whether adverse reaction rates observed in the clinical trials of one drug can be directly compared to rates in the clinical trials of another drug without an effort to adjust for such conditions.

With respect to the applicant's claim that TALVEY™ offers clinically meaningful outcomes in heavily pre-treated patients naïve to prior bsAb and CAR T-cell therapy, we note that the applicant compared the results from MonumenTAL–1, the ongoing TALVEY™ clinical study, with clinical study results of TECVAYLI® and ELREXFIO™.[104] [105] The applicant noted that the overall response rates (ORRs) for TALVEY™'s 0.4 mg/kg weekly and 0.8 mg/kg biweekly cohorts of 74.1 percent and 71.7 percent respectively seem higher than the response rates reported for TECVAYLI® (63 percent) and ELREXFIO™ (61 percent). The applicant also noted the duration of response (DOR), progression free survival (PFS), and overall survival (OS) for TALVEY™ were comparable to that of the BCMA bispecific antibodies. However, we note that this was based on a comparison of three separate clinical trials, which can involve numerous confounding variables, and the applicant did not provide supporting data related to clinical trial design or statistical analysis to explain why the potential effects of confounding variables should not be a concern for purposes of this comparison. Therefore, we are interested in additional evidence demonstrating that TALVEY™ significantly improves clinical outcomes compared to BCMA bispecific antibodies in heavily pre-treated patients naïve to prior bispecific antibody and CAR T-cell therapy that adjusts for the effects of confounding factors.

With respect to the applicant's claim that TALVEY™ offers clinically meaningful outcomes in patients exposed to prior bispecific antibody and CAR T-cell therapy, the applicant referenced past results from MonumenTAL–1 that included a cohort of 51 patients with prior T-cell redirection therapies (TCR) including BCMA-directed CAR–T therapies and/or bispecific antibodies, citing an ORR of 64.7 percent in these heavily pre-treated patients.[106] The applicant also provided updated results that included an additional 19 patients with prior TCR that demonstrated similar efficacy, noting slightly higher ORRs and improved PFS and DOR rates in patients with prior BCMA CAR T-cell versus prior bispecific antibody therapies. We welcome additional information demonstrating the efficacy of TALVEY™ in patients previously treated with BCMA-directed TCRs.

We are inviting public comments on whether TALVEY™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TALVEY™.

l. Odronextamab, First Indication: Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)

Regeneron Pharmaceuticals, Inc. submitted an application for new technology add-on payments for odronextamab for use in relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) for FY 2025. According to the applicant, odronextamab is the first and only novel, fully-human Cluster of Differentiation (CD) 20 × CD 3 bispecific antibody (bsAb) with an immunoglobulin G4 (IgG4)-based structure in B-Cell non-Hodgkin lymphoma (B–NHL) created using Regeneron's proprietary Veloci-Bi® technology that is designed to simultaneously bind to two types of antigens, CD20 found on both healthy and cancerous B cells, and CD3 found on T-cells. Per the applicant, simultaneous engagement of both arms of odronextamab results in the activation of immune system T-cells, causing it to generate cytotoxic T-cells that can destroy the targeted cells, including cancerous B-cells. We note that Regeneron Pharmaceuticals, Inc. also submitted an application for new technology add-on payments for odronextamab for use in relapsed or refractory follicular lymphoma (R/R FL) for FY 2025, as discussed separately later in this section.

Please refer to the online application posting for odronextamab, available at *https://mearis.cms.gov/public/publications/ntap/NTP231017LHBUG,* for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated that its marketing authorization request for odronextamab has been filed by FDA and that it anticipates a Biologic License Application (BLA) decision from FDA for adults with R/R DLBCL after at least two prior systemic therapies, including patients with or without prior CAR T-cell therapy, before May 1, 2024. According to the applicant, odronextamab will be commercially available immediately after FDA approval. According to the applicant, it anticipates that inpatient usage of odronextamab might occur due to a physician's order or as a result of an adverse event, such as cytokine release syndrome (CRS) Grade 2 or higher, that results in an inpatient admission. The applicant noted that in the pivotal Phase 2 clinical trial (ELM–2), when CRS Grade 2 or 3 events developed among DLBCL patients (there were no CRS Grade 4 or higher reported on the recommended dosing regimen), 31 percent of the time it occurred after the initial dose (0.7 mg), 46 percent after the first intermediate dose (4 mg), 15 percent after the second intermediate dose (20 mg), 0 percent after the first full dose (160 mg), and 8 percent after the second full dose & beyond (160 mg). Using this information, the applicant developed a weighted average inpatient dose of 17.4 mg.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify odronextamab. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for odronextamab beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify this indication for odronextamab under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. We believe the relevant ICD–10–CM codes to identify the indication of R/R DLBCL would be the codes included in category C83 (Non-follicular lymphoma) under the ICD–10–CM classification in subcategory: C83.3- (Diffuse large B-cell

[104] Van de Donk, N, Moreau, P, Garfall, AL, et al. Long term follow-up from MajesTEC–1 of Teclistamab, a BCMAxCD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma. 2023 American Society of Clinical Oncology Annual Meeting, Poster #8011.

[105] Mohty, M, Tomasson, MH, and Arnulf, B, et al. Elranatamab, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, for patients with relapsed/refractory multiple myeloma: Extended follow-up and bi-weekly administration from the MagnetisMM–3 study. 2023 American Society of Clinical Oncology Annual Meeting, Poster #8039.

[106] Jakubowiak, AJ, Anguille, S, Karlin, L, et al. Updated Results of Talquetamab, a GPRC5D×CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma with prior exposure to T-Cell redirecting therapies: results of the Phase ½ MonumenTAL–1 Study 2023 American Society of Hematology Annual Meeting. Poster #3377.

lymphoma). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of R/R DLBCL for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that odronextamab is not substantially similar to other currently available technologies. According to the applicant, the mechanism of action for odronextamab presents noteworthy distinctions, such as reduced potential for immunogenicity and anti-drug antibodies through its novel fully human design and reduced ability to elicit an immune response through the blocking effect of the IgG4-based structure. The applicant also asserted that odronextamab is the only bispecific antibody (bsAb) with a dedicated prospective cohort that shows efficacy in patients with R/R DLBCL with prior CAR T-cell therapy while also showing comparable efficacy in patients without prior CAR T-cell therapy, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for odronextamab for the applicant's complete statements in support of its assertions that odronextamab is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	Yes	Odronextamab is a fully human, IgG4-based, CD20xCD3 bsAb that binds to CD20, a B-cell surface antigen present on normal and malignant B-cells and CD3, a T-cell receptor. Simultaneous engagement of both arms of odronextamab results in formation of a synapse between the T-cell and the CD20-expressing cell, triggering T-cell activation and cytotoxic T-cell response, which results in targeted T-cell killing of B-cells. Epcoritamab and glofitamab are CD20xCD3 bsAbs indicated for the treatment of patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. While Regeneron recognizes that odronextamab, epcoritamab, and glofitamab share a common mechanism of action, it is important to note key distinctions. Odronextamab is the first and only fully human, IgG4-based bsAb in B-NHL created using Regeneron's proprietary Veloci-Bi® technology. The fully human design may help reduce potential for immunogenicity and anti-drug antibodies, distinguishing it from epcoritamab and glofitamab, which are humanized IgG1-based bsAbs.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Odronextamab will likely be assigned to the MS-DRGs 840, 841, 823, 820, 824, 016, 018, 821, 842, 825, 822, 014,004 similar to existing technologies used to treat R/R DLBCL. This is due to the non-specificity of the MS-DRG system to differentiate between patients diagnosed with different lymphomas. This is further explained in the cost criterion section of the application, where we identified potential odronextamab utilization using ICD-10-CM diagnosis codes that mapped to the 12 MS-DRGs noted previously.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	Odronextamab is a fully human, IgG4-based, CD20xCD3 bsAb developed by Regeneron Pharmaceuticals for the treatment of adult patients with R/R DLBCL after at least two prior systemic therapies, including patients with or without prior CAR T-cell therapy. Odronextamab is designed to bind to CD20, a B-cell surface antigen present on normal and malignant B-cells and CD3, a T-cell receptor. Simultaneous engagement of both arms of odronextamab results in the formation of a synapse between the T-cell and the CD20-expressing cell, triggering T-cell activation and cytotoxic T-cell response, which results in the targeted T-cell killing of B-cells. DLBCL is classified into stages I-IV and an estimated 55% of patients with DLBCL are diagnosed with stage III/IV disease. Currently available therapies such as epcoritamab and glofitamab are suggested treatment regimens in patients with disease progression after transplant or CAR T-cell therapy in patients with R/R DLBCL. Odronextamab is the only bsAb with a dedicated prospective cohort that shows efficacy in patients with R/R DLBCL with prior CAR T-cell therapy based on a Phase 1 open-label, multi-center, multi-cohort study.

We note that according to the applicant, odronextamab may have a similar mechanism of action to that of EPKINLY™ (epcoritamab) and COLUMVI™ (glofitamab), for which we approved an application for new technology add-on payments for FY 2024 (88 FR 58835) for the treatment of adult patients with R/R DLBCL after two or more prior lines of systemic therapy. Specifically, a similar IgG bsAb engaging CD3 × CD20 mechanism is utilized in the treatment of the same population of R/R DLBCL adult patients with two or more prior therapies. Although the applicant asserts that odronextamab is the first and only fully human, IgG4-based bsAb in B–NHL, which may help reduce potential for immunogenicity and anti-drug antibodies, we believe that this would relate to the risk of adverse event from odronextamab administration but is not critical to the way the drug treats the underlying disease, and therefore would relate to an assessment of substantial clinical improvement, rather than of substantial similarity.

The applicant asserts that it treats a new patient population because it is indicated for a sub-population of patients within R/R DLBCL: adult patients with two or more prior therapies after transplant or CAR T-cell therapy. However, as noted by the applicant, both EPKINLY™ and COLUMVI™ may also be used for patients with R/R DLBCL with disease progression after transplant or CAR T-cell therapy, also after two or more lines of systemic therapies. Therefore, we believe that odronextamab may treat the same or similar disease in the same or similar patient population as EPKINLY™ and COLUMVI™. Accordingly, as it appears that odronextamab, and EPKINLY™ and COLUMVI™ may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if we determine that this technology is substantially similar to EPKINLY™ and COLUMVI™, we believe the newness period for this technology would begin on May 19, 2023, the date on which EPKINLY™ received FDA approval, which is the earliest market availability date submitted for EPKINLY™ and COLUMVI™. We are interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.

We are inviting public comments on whether odronextamab meets the newness criterion, including whether odronextamab is substantially similar to EPKINLY™ and COLUMVI™ or other existing technologies.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR using a combination of ICD–10–CM and/or PCS codes to identify potential cases representing patients who may be eligible for odronextamab. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the tables later in this section.

For the first analysis, the applicant used a list of ICD–10–CM diagnosis codes to identify cases with primary diagnosis of DLBCL. The applicant excluded cases with a corresponding ICD–10–CM or ICD–10–PCS code indicating active treatment. Per the applicant, active treatment was defined as allogeneic stem cell transplant, bone marrow transplant, transplant complications, chemotherapy administration, immunotherapy, or radiation. Please see the online posting for odronextamab for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 3,066 claims mapping to 10 MS–DRGs, including MS–DRG 840 (Lymphoma and Non-Acute Leukemia with MCC) representing 34.9 percent of the identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $141,787, which exceeded the average case-weighted threshold amount of $106,031.

For the second analysis, the applicant identified cases using a list of ICD–10–CM diagnosis codes: T80.89XA (Other complications following infusion, transfusion, and therapeutic injection) or D89.832–D89.839 (Cytokine release syndrome (CRS) Grades 2–5 or unspecified) in any position. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 80 claims mapping to two MS–DRGs: 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) and 811 (Red Blood Cell Disorders with MCC). The applicant calculated a final inflated average case-weighted standardized charge per case of $1,095,920, which exceeded the average case-weighted threshold amount of $936,675.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant maintained that odronextamab meets the cost criterion.

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ODRONEXTAMAB COST ANALYSIS	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	Scenario 1: C83.30 (Diffuse large B-cell lymphoma, unspecified site) C83.31 (Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck) C83.32 (Diffuse large B-cell lymphoma, intrathoracic lymph nodes) C83.33 (Diffuse large B-cell lymphoma, intra-abdominal lymph nodes) C83.34 (Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb) C83.35 (Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb) C83.36 (Diffuse large B-cell lymphoma, intrapelvic lymph nodes) C83.37 (Diffuse large B-cell lymphoma, spleen) C83.38 (Diffuse large B-cell lymphoma, lymph nodes of multiple sites) C83.39 (Diffuse large B-cell lymphoma, extranodal and solid organ sites) Scenario 2: T80.89XA (Other complications following infusion, transfusion and therapeutic injection, initial encounter) D89.832 (Cytokine release syndrome, grade 2) D89.833 (Cytokine release syndrome, grade 3) D89.834 (Cytokine release syndrome, grade 4) D89.835 (Cytokine release syndrome, grade 5) D89.839 (Cytokine release syndrome, grade unspecified)
List of ICD-10-PCS codes	Scenario 1: For the list of excluded ICD-10-PCS codes, see the online posting for odronextamab. Scenario 2: N/A
List of MS-DRGs	Scenario 1: 840 (Lymphoma and Non-Acute Leukemia with MCC) 841 (Lymphoma and Non-Acute Leukemia with CC) 823 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC) 820 (Lymphoma and Leukemia with Major O.R. Procedures with MCC) 824 (Lymphoma and Non-Acute Leukemia with Other Procedures with CC) 016 (Autologous Bone Marrow Transplant with CC/MCC) 821 (Lymphoma and Leukemia with Major O.R. Procedures with CC) 842 (Lymphoma and Non-Acute Leukemia without CC/MCC) 825 (Lymphoma and Non-Acute Leukemia with Other Procedures without CC/MCC) 822 (Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC) Scenario 2: 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) 811 (Red Blood Cell Disorders with MCC)
Inclusion/ exclusion criteria	Scenario 1: The applicant identified cases from any MS-DRG with a primary ICD-10-CM diagnosis of DLBCL without a corresponding ICD-10-CM or ICD-10-PCS code indicating active treatment, using the list provided by the applicant in the online posting. Per the applicant, the selected cases best represent patients with r/r DLBCL, who are not receiving other active treatment and are admitted inpatient for the purposes of being administered odronextamab based on the clinical judgment of their provider. Scenario 2: The applicant identified cases from any MS-DRG with an ICD-10-CM diagnosis code listed previously in any position. Per the applicant, the selected cases best represent potential patients who, as a result of developing CRS following outpatient administration of odronextamab, require an inpatient admission within the three-day payment window. For both scenarios, the applicant excluded MS-DRGs with case volume less than 11 total cases.
Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

We are inviting public comments on whether odronextamab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that odronextamab represents a substantial clinical improvement over existing technologies because odronextamab offers a new treatment for patients who are ineligible for CAR T-cell therapy and represents a substantial clinical improvement over existing technologies in patients with R/R DLBCL, including those with or without prior CAR T-cell therapy. According to the applicant, odronextamab will expand access to heavily pretreated, highly refractory patients and will offer patients with R/R DLBCL a new monotherapy that demonstrates substantial clinical benefits, including a generally manageable safety profile and favorable Health Related Quality of Life (HRQoL). The applicant also asserted that odronextamab significantly improves clinical outcomes relative to services or technologies previously available (such as EPKINLY™ and COLUMVI™). The applicant provided three studies to support these claims, as well as nine background articles about other therapies.[107] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for odronextamab for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[107] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
Odronextamab will increase treatment options for patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) who have a high risk of cytokine release syndrome (CRS).	Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Odronextamab monotherapy is an effective treatment option for patients with R/R DLBCL including those with or without prior CAR T-cell therapy.	Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
The odronextamab clinical program enrolled heavily pre-treated and highly refractory patients with high-grade NHL and a worse ECOG performance status.	Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Odronextamab is the first CD20xCD3 bsAb to report long-term patient outcomes at longest follow-up of 4.5 years.	Bannerji R, Arnason JE, Advani RH, et al. Odronextamab, a human CD20×CD3 bsAb in patients with CD20-positive B-cell malignancies (ELM-1): results from the relapsed or refractory non-Hodgkin lymphoma cohort in a single-arm, multicentre, phase 1 trial. The Lancet Haematol. 2022;9(5):e327-e339. doi:10.1016/s2352-3026(22)00072-2.
Odronextamab treatment until disease progression may have benefits on HRQoL for heavily pretreated patients with R/R DLBCL and potentially addresses unmet needs in a challenging treatment setting.	Iskierka-Jażdżewsk E, Kim W, Cho S, et al. Health-Related Quality of Life and Symptoms in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma Treated with Odronextamab Monotherapy in the Phase 2 ELM-2 Study. Abstract presented at: American Society of Hematology (ASH) Annual Meeting and Exposition. December 2023. San Diego, CA.

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After review of the information provided by the applicant, we have the following concerns regarding whether odronextamab meets the substantial clinical improvement criterion. We note that with respect to the claim that odronextamab will increase treatment options for patients with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) who have a high risk of cytokine release syndrome (CRS), the applicant submitted the oral presentation slides of the results from a pre-specified analysis by Kim et al. (2022),[108] presenting the interim results for the Phase II trial for odronextamab, ELM–2. In this trial, 140 patients (median age: 66 years) with R/R DLBCL after 2 or more lines of therapy, Eastern Cooperative Oncology Group (ECOG) 0 or 1, were assigned to receive either a

[108] Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM–2. Presented at American Society of Hematology (ASH). December 12, 2022.

1/20 mg step-up regimen (n = 67) or 0.7/4/20 mg step-up regimen (n = 73) after the study initiated with a first cycle of step-up regimen of 1/20 mg. The regimen was modified to 0.7/4/20 mg during Cycle 1 to further mitigate the risk of CRS. The rates of CRS grades 2 and 3 for patients grouped to the 1/20 regimen were 17.9 percent and 7.5 percent respectively, while rates of CRS grades 2 and 3 for patients grouped to the 0.7/4/20 regimen were 13.7 percent and 1.4 percent. We note that although the incidence of grade 3 CRS was lower in the 0.7/4/20 regimen arm, the applicant indirectly compared these incidence rates with the rates of trials as found in the prescribing information for other existing technologies, including EPKINLY™ and COLUMVI™, and it is unclear if these differences are statistically significant. We also question whether there are differences between these clinical trials, such as patient characteristics or other confounding variables, which would limit such comparability between CRS incidence rates. We are concerned as to whether the differences identified by the applicant translate to clinically meaningful improvements for patients treated with odronextamab as compared to rates for existing treatments.

With respect to the claim that odronextamab monotherapy is an effective treatment option for patients with R/R DLBCL including those with or without prior CAR T-cell therapy, the applicant submitted the oral presentation slides of the results from a pre-specified analysis by Kim et al. (2022),[109] previously described. The oral presentation slides refer to the Phase 1 trial for odronextamab (ELM–1) and indicate consistency of results across trials. The applicant noted that patients with prior CAR–T therapy demonstrated an objective response rate (ORR) of 48.4 percent (95 percent CI: 30.2, 66.9), and a Complete Response (CR) rate of 32.3 percent (n = 44 patients). The applicant cited other information about CD20×CD3 bsAbs in patients with R/R DLBCL including the United States Prescribing Information (USPI) for EPKINLY™ and COLUMVI™ for which 29 percent and 30 percent of patients respectively were refractory to CAR T-cell therapy. We note that the provided evidence did not compare the efficacy of odronextamab to EPKINLY™ or COLUMVI™. Similar to our earlier concern, we question whether there are confounding factors between studies that would limit indirect comparisons of ORR and CR. We would be interested in additional evidence to assess the use of odronextamab in improving these clinical outcomes relative to existing treatments.

With respect to the claim that the odronextamab clinical program enrolled heavily pre-treated and highly refractory patients with high-grade non-Hodgkins Lymphoma (NHL) and sicker patients based on a worse ECOG performance status, the applicant submitted the oral slides of the results from a pre-specified analysis by Kim et al. (2022),[110] previously described, and the peer-reviewed publication of the EPKINLY™ dose expansion cohort of the phase I/II clinical trial. ECOG performance status is based on a five-point scale, with higher numbers indicating greater disability. Both trials included patients with ECOG performance status of 0 or 1 and the EPKINLY™ trial also included ECOG performance status scores of 2; the odronextamab trial (n = 140) had rates of 32.1 percent and 67.9 percent for ECOG 0 and 1 respectively, whereas the EPKINLY™ trial has ECOG performance status scores of 47.1 percent, 49.7 percent, and 3.2 percent for ECOG 0, 1, and 2 respectively. However, we note that these incidence rates of patient characteristics are indirectly compared across unrelated clinical trials and patient outcomes are not stratified in either trial based on these characteristics. For example, we note that the classification of ''worse ECOG status'' in the odronextamab trial had a higher incidence rate of patients with ECOG 1 performance status, but this trial did not include patients with ECOG 2 performance status, as did the EPKINLY™ trial.

With regards to the applicant's assertions that odronextamab significantly improves clinical outcomes relative to existing technologies because it is the first CD20×CD3 bsAb to report long-term patient outcomes at longest follow-up of 4.5 years, and that treatment until disease progression may have benefits on HRQoL for heavily pretreated patients with R/R DLBCL and potentially addresses unmet needs in a challenging treatment setting, we are concerned that the evidence presented does not compare these outcomes to existing technologies, such as EPKINLY™ or COLUMVI™. For example, although the applicant stated that odronextamab is the first to report on long-term patient outcomes with the longest follow-up, there does not appear to be evidence demonstrating comparisons of long-term patient outcomes of odronextamab to existing technologies to support its claim that the technology improves clinical outcomes. In addition, there does not appear to be evidence of a direct HRQoL comparison to existing technologies to assess improvements to HRQoL for heavily pretreated patients with R/R DLBCL. Therefore, we welcome additional evidence demonstrating comparisons of odronextamab to existing technologies to support the applicant's claims.

We are inviting public comments on whether odronextamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for odronextamab.

m. Odronextamab, Second Indication: Relapsed or Refractory Follicular Lymphoma (R/R FL)

Regeneron Pharmaceuticals, Inc. submitted an application for new technology add-on payments for odronextamab for use in relapsed or refractory follicular lymphoma (R/R FL) for FY 2025. According to the applicant odronextamab is the first and only novel, fully-human Cluster of Differentiation (CD) 20 × CD 3 bispecific antibody (bsAb) with an immunoglobulin G4 (IgG4)-based structure in B-Cell non-Hodgkin lymphoma (B–NHL) created using Regeneron's proprietary Veloci-Bi® technology that is designed to simultaneously bind to two types of antigens, CD20, found on both healthy and cancerous B cells, and CD3, found on T-cells. Per the applicant, simultaneous engagement of both arms of odronextamab results in the activation of immune system T-cells, causing it to generate cytotoxic T-cells that can destroy the targeted cells, including cancerous B cells. As previously discussed earlier in this section, Regeneron Pharmaceuticals, Inc. also submitted an application for new technology add-on payments for odronextamab for use in relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) for FY 2025.

Please refer to the online application posting for odronextamab, available at *https://mearis.cms.gov/public/*

[109] Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM–2. Presented at American Society of Hematology (ASH). December 12, 2022.

[110] Kim W, Kim T, Cho S, et al. Odronextamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL): results from a prespecified analysis of the pivotal Phase II study ELM–2. Presented at American Society of Hematology (ASH). December 12, 2022.

publications/ntap/NTP231017YATW9, for additional detail describing the technology and B–NHL R/R FL.

With respect to the newness criterion, the applicant stated that its marketing authorization request for odronextamab has been filed by FDA and that it anticipates a Biologic License Application (BLA) decision from FDA for adults with R/R FL after at least two prior systemic therapies, before May 1, 2024. According to the applicant, odronextamab will be commercially available immediately after FDA approval. According to the applicant, it anticipates that inpatient usage of odronextamab might occur due to a physician's order or as a result of an adverse event, such as cytokine release syndrome (CRS) Grade 2 or higher, that results in an inpatient admission. The applicant noted that in the pivotal Phase 2 clinical trial (ELM–2), when CRS Grade 2 or 3 events developed among FL patients (there were no CRS Grade 4 or higher reported on the recommended dosing regimen), 20 percent of the time they occurred after the initial dose (0.7 mg), 50 percent of the time after the first intermediate dose (4 mg), 20 percent of the time after the second intermediate dose (20 mg), 0 percent of the time after the first full dose (80 mg), and 10 percent of the time after the second full dose and beyond (80 mg). Using this information, the applicant developed a weighted average inpatient dose of 14.1 mg.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify odronextamab. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for odronextamab beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify this indication for odronextamab under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. We believe the relevant ICD–10–CM codes to identify the indication of R/R FL would be the codes included in category C82 (Follicular lymphoma) under the ICD–10–CM classification in subcategories: C82.0—(Follicular lymphoma grade I), C82.1—(Follicular lymphoma grade II), C82.2—(Follicular lymphoma grade III, unspecified), C82.3—(Follicular lymphoma grade IIIa), C82.4—(Follicular lymphoma grade IIIb), C82.5—(Diffuse follicle center lymphoma), C82.6—(Cutaneous follicle center lymphoma), C82.8—(Other types of follicular lymphoma), or C82.9—(Follicular lymphoma, unspecified). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of R/R FL for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that odronextamab is not substantially similar to other currently available technologies because its mechanism of action presents notable distinctions, such as reduced potential for immunogenicity and anti-drug antibodies through its novel, fully human design and reduced ability to elicit an immune response through the blocking effect of the IgG4-based structure. The applicant further asserted that odronextamab also has demonstrated efficacy in patients with FL Grade 3b, which were excluded from the GO29781 study of mosunetuzumab, and offers consistent efficacy in other high-risk subgroups of patients with R/R FL, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for odronextamab for the applicant's complete statements in support of its assertion that odronextamab is not substantially similar to other currently available technologies.

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Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	Yes	Odronextamab is a fully human, IgG4-based, CD20xCD3 bsAb that binds to CD20, a B-cell surface antigen present on normal and malignant B-cells and CD3, a T-cell receptor. Simultaneous engagement of both arms of odronextamab results in formation of a synapse between the T-cell and the CD20-expressing cell, triggering T-cell activation and cytotoxic T-cell response, which results in targeted T-cell killing of B-cells. Mosunetuzumab is the only CD20×CD3 bsAb approved in patients with R/R FL Grade 1–3a who had received ≥2 prior lines of therapy. While Regeneron recognizes that odronextamab and mosunetuzumab share a common mechanism of action, it is important to note key distinctions. Odronextamab is the first and only fully human, IgG4-based bsAb in B-NHL created using Regeneron's proprietary Veloci-Bi® technology. IgG4-based bsAbs provide additional binding sites and are referred to as "blocking antibodies" because of their reduced ability to elicit an inflammatory immune response.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Potential odronextamab utilization spanned across nine MS-DRGs in the cost analysis section of this application. These include MS-DRGs 840, 841, 824, 823, 821, 825, 820, 822, 842 similar to existing technologies used to treat R/R FL. This is due to the non-specificity of the MS-DRG system to differentiate between patients diagnosed with different lymphomas and not a reflection of the newness of odronextamab.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	Odronextamab is a fully human, IgG4-based, CD20xCD3 bsAb developed by Regeneron Pharmaceuticals for the treatment of adult patients with relapsed or refractory follicular lymphoma (R/R FL) after at least two prior systemic therapies and relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL) after at least two prior systemic therapies, including patients with or without prior CAR T therapy. Odronextamab is designed to bind to CD20, a B-cell surface antigen present on normal and malignant B-cells and CD3, a T-cell receptor. FL Grade 3b has a median overall survival (OS) of less than 5 years and is treated similarly to diffuse large B-cell. Despite the availability of various treatments for adult patients with R/R FL, controversy exists regarding the management of FL Grade 3. In the "Other B-NHL" cohort of the ELM-2 study, odronextamab demonstrated efficacy in six patients with FL Grade 3b disease. Though the sample size is small, odronextamab demonstrated 100% objective response rate [95% CI: 54.1-100] in all six patients, with a complete response rate of 83.3% as of data cut-off date January 31, 2023. Currently available therapies for patients with R/R FL who have had two or more prior therapies may be appropriate for certain patients, however, substantial clinical factors impact whether a patient may benefit from third line or subsequent treatment options. Mosunetuzumab is the only CD20×CD3 bsAb approved in patients with R/R FL Grade 1–3a who had received two or more prior therapies. While cross-trial comparisons should be treated with caution, select baseline characteristics of patients in the FL cohort of the ELM-2 study were less favorable when compared with those in the GO29781 study of mosunetuzumab. More patients in the ELM-2 study were aged ≥65 years, had prior autologous stem cell transplant, Ann Arbor stage III–IV, FLIPI score of 3-5, and ECOG PS 1, as compared with Study GO29781 of mosunetuzumab.

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With regard to the newness criterion, we note that according to the applicant odronextamab may have a similar mechanism of action to that of Lunsumio™ (mosunetuzumab), another IgG bsAb engaging CD3×CD20, for which we approved an application for new technology add-on payments for FY 2024 (88 FR 58844), which treats the same population of R/R FL adult patients with two or more prior therapies. Although the applicant states that there are key distinctions between the mechanism of action of odronextamab and Lunsumio™ because odronextamab is the first and only fully human, IgG4-based bsAb, which provides additional binding sites and reduces its ability to elicit an inflammatory immune response, we do not believe that the number of binding sites results in a different mechanism of action. We also believe that a reduction in inflammatory immune response would relate to the risk of an adverse event from odronextamab administration but is not critical to the way the drug treats the underlying disease, and therefore would relate to an assessment of substantial clinical improvement, rather than of substantial similarity.

The applicant asserted that odronextamab treats a sub-population of patients within the R/R FL adult

patients with two or more prior therapies in its summary, specifically, that of R/R FL Grade 3b—a rare subgroup of patients who are generally excluded from clinical trials.[111] However, we note that the FDA-approved labeling for Lunsumio™ does not appear to exclude this patient population. As such, it is unclear whether odronextamab would treat a patient population different from other CD20 × CD3 IgG bsAbs that treat patients with R/R FL, such as Lunsumio™. Accordingly, as it appears that odronextamab and Lunsumio™ may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that if we determine that this technology is substantially similar to Lunsumio™, we believe the newness period for this technology would begin on December 22, 2022, the date Lunsumio™ received FDA approval.

We are inviting public comments whether odronextamab meets the newness criterion, including whether odronextamab is substantially similar to Lunsumio™ or other existing technologies.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR using a combination of ICD–10–CM and/or PCS codes to identify potential cases representing patients who may be eligible for odronextamab. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the tables later in this section.

For the first analysis the applicant used a list of ICD–10–CM diagnosis codes to identify cases with primary diagnoses of follicular lymphoma. The applicant excluded cases with a corresponding ICD–10–CM or ICD–10–PCS code indicating active treatment. Per the applicant, active treatment was defined as allogeneic stem cell transplant, bone marrow transplant, transplant complications, chemotherapy administration, immunotherapy, or radiation. Please see the online posting for odronextamab for the complete list of codes provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 482 claims mapping to nine MS–DRGs, including MS–DRG 840 (Lymphoma and Non-Acute Leukemia with MCC) representing 29.3 percent of the identified cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $101,177 which exceeded the average case-weighted threshold amount of $95,779.

For the second analysis the applicant identified cases using a list of ICD–10–CM diagnosis codes: T80.89XA (Other complications following infusion, transfusion, and therapeutic injection) or D89.832–D89.839 (Cytokine release syndrome (CRS) Grades 2–5 or unspecified) in any position. The applicant used the inclusion/exclusion criteria described in the table later in this section. Under this analysis, the applicant identified 80 claims mapping to two MS–DRGs, including 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) and 811 (Red Blood Cell Disorders with MCC). The applicant calculated a final inflated average case-weighted standardized charge per case of $1,095,920, which exceeded the average case-weighted threshold amount of $963,675.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that odronextamab meets the cost criterion.

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[111] Barraclough A, England JT, Villa D, Wight J, Hapgood G, Conn J, Doo NW, Li EW, Gilbertson M, Shaw B, Bishton MJ, Saeed M, Ratnasingam S, Abeyakoon C, Chong G, Wai SH, Ku M, Lee HP, Fleming K, Tam C, Douglas G, Cheah CY, Ng ZY, Rolfe T, Mills AK, Hamad N, Cashman H, Gleeson M, Narayana M, Hawkes EA. Outcomes in grade 3B follicular lymphoma: an international study led by the Australasian Lymphoma Alliance. Haematologica. 2023 Sep 1;108(9):2444–2453.

ODRONEXTAMAB COST ANALYSIS[112]	
Data Source and Time Period	FY 2022 MedPAR File
List of ICD-10-CM codes	Scenario 1: For the list of ICD-10-CM codes, included and excluded, see the online posting for odronextamab. Scenario 2: T80.89XA (Other complications following infusion, transfusion and therapeutic injection, initial encounter) D89.832 (Cytokine release syndrome, grade 2) D89.833 (Cytokine release syndrome, grade 3) D89.834 (Cytokine release syndrome, grade 4) D89.835 (Cytokine release syndrome, grade 5) D89.839 (Cytokine release syndrome, unspecified)
List ICD-10-PCS codes	Scenario 1: For the list of excluded ICD-10-PCS codes, see the online posting for odronextamab. Scenario 2: N/A
List of MS-DRGs	Scenario 1: 840 (Lymphoma and Non-Acute Leukemia with MCC) 841 (Lymphoma and Non-Acute Leukemia with CC) 824 (Lymphoma and Non-Acute Leukemia with Other Procedures with CC) 823 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC) 821 (Lymphoma and Leukemia with Major O.R. Procedures with CC) 825 (Lymphoma and Non-Acute Leukemia with Other Procedures without CC/MCC) 820 (Lymphoma and Non-Acute Leukemia with Major O.R. Procedures with MCC) 822 (Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC) 842 (Lymphoma and Non-Acute Leukemia without CC/MCC) Scenario 2: 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies) 811 (Red Blood Cell Disorders with MCC)
Inclusion/ exclusion criteria	Scenario 1: The applicant identified cases from any MS-DRG with a primary ICD-10-CM diagnosis of follicular lymphoma without a corresponding ICD-10-CM or ICD-10-PCS code indicating active treatment, using the list provided by the applicant in the online posting. Per the applicant, the selected cases best represent patients with R/R FL, who are not receiving other active treatment and who are admitted as inpatients for the purposes of being administered odronextamab based on the clinical judgment of their provider. Scenario 2: The applicant identified cases from any MS-DRG with an ICD-10-CM diagnosis code listed previously in any position. Per the applicant, the selected cases best represent patients who, as a result of developing CRS following outpatient administration of odronextamab, require an inpatient admission within the three-day payment window. For both scenarios, the applicant excluded MS-DRGs with case volume less than 11 total cases.
Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

We are inviting public comments on whether odronextamab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that odronextamab represents a substantial clinical improvement over existing technologies because it will expand access to heavily pretreated, highly refractory patients for whom existing therapies are not adequate. According to the applicant, treatment with odronextamab offers patients with R/R FL a new, readily available monotherapy that demonstrates multiple substantial clinical benefits, including a generally manageable safety profile, and establishes a new benchmark for efficacy. The applicant also asserted that odronextamab significantly improves clinical outcomes relative to services or technologies previously available (such as Lunsumio™). The applicant provided three studies to support these claims, as well as eight background articles about other therapies for the R/R FL patient population.[113] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for odronextamab for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[112] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

[113] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Applicant statements in support	**Supporting evidence provided by the applicant**
Odronextamab will increase treatment options for patients with relapsed or refractory follicular lymphoma (R/R FL) who have a high risk of cytokine release syndrome (CRS).	Kim Tae Min, Taszner Michal, Cho Seok-Goo, et al. Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Odronextamab offers patients with heavily pretreated, highly refractory FL a new, readily available, monotherapy that establishes a new benchmark for efficacy.	Kim Tae Min, Taszner Michal, Cho Seok-Goo, et al. Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Odronextamab demonstrated efficacy in patients with FL Grade 3b disease in the ELM-2 study	FL Grade 3B Post-Text Tables. Regeneron Pharmaceuticals, Inc.
Patients in the FL cohort of the ELM-2 study exhibited more unfavorable select baseline characteristics compared to those in the mosunetuzumab study.	Kim Tae Min, Taszner Michal, Cho Seok-Goo, et al. Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: results from a prespecified analysis of the pivotal Phase II study ELM-2. Presented at American Society of Hematology (ASH). December 12, 2022. Budde L, Sehn L, et al. Safety and efficacy of mosunetuzumab, a bsAb, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. The Lancet Oncology. 2022; 23: 1055065. https://doi.org/10.1016/S1470-2045(22)00335-7 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Odronextamab is the first CD20xCD3 bsAb to report long-term patient outcomes at longest follow-up of 4.5 years.	Cao Y, Marcucci EC, Budde LE. Mosunetuzumab and lymphoma: latest updates from 2022 ASH annual meeting. J Hematol Oncol. 2023;16(1):69. Published 2023 Jun 28. doi:10.1186/s13045-023-01462-0 The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Patient-reported HRQoL were favorable during odronextamab treatment until disease progression, without adversely affecting patient-reported symptoms, functioning, overall quality of life.	Tessoulin B, Cho S, Taszner M, et al. Maintenance of Moderate to High Levels of Functioning and Quality of Life with Odronextamab Monotherapy in Patients with Relapsed or Refractory Follicular Lymphoma. Abstract presented at: American Society of Hematology (ASH) Annual Meeting and Exposition. December 2023. San Diego, CA.

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After review of the information provided by the applicant, we have the following concerns regarding whether odronextamab meets the substantial clinical improvement criterion. We note that with respect to the claim that odronextamab will increase treatment options for patients with R/R FL who have a high risk of CRS, the applicant submitted the oral presentation slides of the results from a pre-specified analysis by Kim et al. (2022),[114] presenting the

[114] Kim Tae Min, Taszner Michal, Cho Seok-Goo, et al. Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: results from a prespecified analysis of the pivotal Phase II study ELM–2. Presented at

interim results for the Phase II trial for odronextamab on the FL cohort, ELM–2. In this Phase II trial, 131 patients (median age: 61 years) with R/R FL after two or more lines of therapy were grouped to receive a 1/20 mg step-up regimen (n = 68) or 0.7/4/20 mg step-up regimen (n = 53) after the study initiated with a first cycle of step-up regimen of 1/20 mg. The regimen was modified to 0.7/4/20 mg during Cycle 1 to further mitigate the risk of CRS. The rates of CRS grades 2 and 3 for the 1/20 regimen are 17.6 percent and 5.9 percent, respectively, compared to the CRS grades 2 and 3 for the 0.7/4/20 regimen of 11.1 percent and 1.6 percent. We note that although the incidence of grade 3 CRS was lower in the 0.7/4/20 regimen arm, the applicant submitted the United States Prescribing Information (USPI) for other therapies (including Lunsumio™ and tisagenlecleucel) used to treat R/R FL patients to provide the CRS rates following treatment with existing therapies. As the applicant indirectly compared these incidence rates with those rates of trials as found in the prescribing information for other existing technologies, it is unclear if these differences are statistically significant. We note that because clinical trials are conducted under widely varying conditions, we question whether adverse reaction rates observed in the clinical trials of one drug can be directly compared to rates in the clinical trials of another drug. We question whether such comparisons across clinical trial cohorts adequately provide evidence of reduced adverse events in patients treated with odronextamab.

Similarly, we note that with respect to the claim that odronextamab offers patients with heavily pretreated, highly refractory FL a new, readily available, monotherapy that establishes a new benchmark for efficacy, the applicant submitted the objective response rates (ORR) and complete response rates (CR) of its Phase II study, ELM–2 and compared them to the ORR and CR rates of the Lunsumio™ GO29781 study. We note the same concerns as with the previous claim about comparing outcomes across studies given the variability in clinical trial design.

With respect to the claim that odronextamab demonstrated efficacy in patients with FL Grade 3b disease in the ELM–2 study, although the applicant provided additional analysis from the ELM–2 study where odronextamab demonstrated efficacy across six patients enrolled in the study with FL Grade 3B, we note that it is unclear whether the additional analysis that was provided in addition to the ELM–2 study represents an ad-hoc analysis, therefore, we are concerned about drawing conclusions from this ad-hoc analysis to appropriately demonstrate efficacy in the FL Grade 3B subgroup. Furthermore, we are concerned that the applicant did not compare the results of the study to the efficacy of existing therapies for patients with FL Grade 3B. We would be interested in additional evidence comparing outcomes between odronextamab and existing therapies such as Breyanzi®, which is also approved for patients with FL Grade 3B with relapsed or refractory disease after two or more lines of systemic therapy.

With respect to the claim that patients in the FL cohort of the ELM–2 study exhibited more unfavorable select baseline characteristics compared to those in the Lunsumio™ study, the applicant presented the analysis for odronextamab by Kim et al. (2022),[115] described previously, and the Lunsumio™ phase 2 study on R/R patients with FL.[116] The applicant stated that patients treated with odronextamab in the ELM–2 cohort had received prior autologous stem cell transplants at a higher rate (30.5 percent) than those treated in the Lunsumio™ study (21%). The applicant also noted additional unfavorable select baseline characteristics for patients in the ELM–2 study compared to patients in the Lunsumio™ study, including: more patients with a worse Eastern Cooperative Oncology Group (ECOG) performance status, as 48.1 percent of patients in ELM–2 had an ECOG performance status of 1, compared to 41 percent of patients in the Lunsumio™ study; more patients with an Ann Arbor stage III–IV (84.7 percent of patients, compared to 77 percent of patients in the Lunsumio™ study); more patients with a FLIPI score of 3–5 (58.8 percent of patients, compared to 44 percent of patients in the Lunsumio™ study); and more older patients, with 38.9 percent of patients ≥65 years old (median age of 61), compared to a median age of 60 for Lunsumio™. We note these are indirect rate comparisons across clinical trials without statistical adjustments performed across the patient populations and clinical outcomes. We also note that differences in patient characteristics across any two clinical trials, even with the same selection criteria, are likely to occur. As such, we question whether the comparison of baseline characteristics across cohorts in independent clinical trials can be taken as indicative of differences in clinical outcomes or efficacy between treatments.

We are inviting public comments on whether odronextamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for odronextamab.

6. Proposed FY 2025 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by the FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2-to-3-year newness period to be considered ''new,'' and must also still meet the cost criterion.

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we

American Society of Hematology (ASH). December 12, 2022.

[115] Kim Tae Min, Taszner Michal, Cho Seok-Goo, et al. Odronextamab in patients with relapsed/refractory (R/R) follicular lymphoma (FL) Grade 1–3a: results from a prespecified analysis of the pivotal Phase II study ELM–2. Presented at American Society of Hematology (ASH). December 12, 2022.

[116] Budde L, Sehn L, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. The Lancet Oncology. 2022; 23: 1055065. *https://doi.org/10.1016/S1470-2045(22)00335-7.*

finalized our proposal to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we are continuing to summarize each application in this proposed rule. However, while we are continuing to provide discussion of the concerns or issues, we identified with respect to applications submitted under the alternative pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the applicable new technology add-on payment criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2025 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2025 new technology add-on payment applications.

We received 23 applications for new technology add-on payments for FY 2025 under the new technology add-on payment alternative pathway. As discussed previously, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958). Of the 23 applications received under the alternative pathway, seven applications were not eligible for consideration for new technology add-on payment because they did not meet these requirements; and two applicants withdrew their applications prior to the issuance of this proposed rule, including the withdrawal of the application for DefenCath™ (taurolidine/heparin), which received conditional approval for new technology add-on payments for FY 2024, subsequently received FDA approval in November 2023, and therefore was eligible to receive new technology add-on payments beginning with discharges on or after January 1, 2024. As discussed in section II.E.4. of this proposed rule, we are proposing to continue making new technology add-on payments for DefenCath™ (taurolidine/heparin) for FY 2025. Of the remaining 14 applications, 12 of the technologies received a Breakthrough Device designation from FDA. The remaining two applications were designated as a QIDP by FDA. We did not receive any applications for technologies approved through the LPAD pathway.

In accordance with the regulations under § 412.87(f)(2), applicants for new technology add-on payments for FY 2025 for Breakthrough Devices must have FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under § 412.87(f)(3), applicants for new technology add-on payments for FY 2025 for QIDPs and technologies approved under the LPAD pathway must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. The policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742) provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2024 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in this proposed rule we are making a proposal to approve or disapprove each of these 14 applications for FY 2025 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide background information on each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2025. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies.

a. Annalise Enterprise Computed Tomography Brain (CTB) Triage—Obstructive Hydrocephalus (OH)

Annalise-Ai Pty Ltd submitted an application for new technology add-on payments for the Annalise Enterprise CTB Triage—OH for FY 2025. According to the applicant, the Annalise Enterprise CTB Triage—OH is a medical device software application used to aid in the triage and prioritization of studies with features suggestive of obstructive hydrocephalus (OH). Per the applicant, the device analyzes studies using an artificial intelligence (AI) algorithm to identify suspected OH findings in non-contrast computed tomography (NCCT) brain scans and makes study-level output available to an order and imaging management system for worklist prioritization or triage.

Please refer to the online application posting for the Annalise Enterprise CTB Triage—OH available at *https://mearis.cms.gov/public/publications/ntap/NTP231017D5AA7,* for additional detail describing the technology and how it is used.

According to the applicant, the Annalise Enterprise CTB Triage—OH received Breakthrough Device designation from FDA on February 17, 2023, for use in the medical care environment to aid in triage and prioritization of studies with features suggestive of OH. The device analyzes studies using an AI algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage. The applicant stated that the technology received 510(k) clearance from FDA on August 15, 2023, for the same indication consistent with the Breakthrough Device designation. Per the applicant, the Annalise Enterprise CTB Triage—OH was not immediately available for sale because there were additional steps to be completed following 510(k) clearance prior to the product becoming commercially available. According to the applicant, these additional steps involved generating a new unique device identifier (UDI) to incorporate the recently cleared finding for OH, integrating this UDI into the device, and

releasing it. Per the applicant, the Annalise Enterprise CTB Triage—OH became commercially available on October 10, 2023.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Annalise Enterprise CTB Triage—OH. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Annalise Enterprise CTB Triage—OH beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the Annalise Enterprise CTB Triage—OH under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided three analyses to demonstrate that the technology meets the cost criterion. The applicant stated that for all three analyses, it used the 2021 Standard Analytic Files (SAF) Limited Data Set (LDS) to identify the top admitting diagnosis codes for inpatient stays that were admitted from the emergency room (ER) and included a non-contrast CT head scan. Next, it searched the FY 2022 MedPAR data to identify applicable inpatient stays based on different sets of admitting diagnosis codes for each of the three analyses. The applicant explained that it used admitting diagnosis codes from the inpatient stays, rather than discharge diagnosis codes, because the Annalise Enterprise CTB Triage—OH is an AI-based technology used to identify and prioritize patients suspected of OH. As a result, it will commonly be used in the ER before the doctor and/or the hospital has assigned the primary or secondary diagnosis for the inpatient stay. The applicant stated that admitting diagnosis codes may be better predictors for whether the Annalise Enterprise CTB Triage—OH service will be used, rather than primary or secondary diagnosis at discharge, which will likely represent information known after the procedure is performed. Per the applicant, for identifying the top admitting diagnosis codes, the inpatient stays were further narrowed down to only those where the patient had a physician claim during the inpatient stay or 1 day before for a non-contrast CT head scan (defined as CPT codes 70450, 70480, 70486), or had an outpatient claim for a non-contrast CT head scan the day of admission or 1 day before. Each analysis followed the order of operations described in the table that follows later in this section.

For the primary analysis, the applicant stated that it searched the FY 2022 MedPAR file for cases with emergency room charges (that is, emergency room charge amount greater than $0) and/or an inpatient admission type code (IP_ADMSN_TYPE_CD) equal to 1 for emergency, and reporting one of the top 25 diagnosis codes associated with 50% of all identified inpatient stays in the 2021 SAF. According to the applicant, it identified 2,206,036 claims mapping to 714 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), which represented 16% of identified cases. The applicant stated that it calculated a final inflated average case-weighted standardized charge per case of $80,407, which exceeded the average case-weighted threshold amount of $69,892.

For the second analysis, the applicant stated that it conducted a sensitivity analysis using cases with emergency room charges (that is, emergency room charge amount greater than $0) and/or an inpatient admission type code (IP_ADMSN_TYPE_CD) equal to 1 for emergency, and reporting one of the top 186 admitting diagnosis codes associated with 80% of all identified inpatient stays in the 2021 SAF LDS. The applicant noted that it identified 3,991,354 claims mapping to 739 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), which represented 11% of identified cases. The applicant noted that it calculated a final inflated average case-weighted standardized charge per case of $78,356, which exceeded the average case-weighted threshold amount of $68,660.

For the third analysis, the applicant stated that it conducted a sensitivity analysis that identified cases using the same criteria as the primary analysis, and further limited it to cases that also incurred CT charges. Per the applicant, it performed this sensitivity analysis because although doctors are likely to order the Annalise AI technology when a NCCT head scan is performed and the patient is admitted through the emergency room, the MedPAR file variable for CT charges does not differentiate between contrast and NCCTs, or the area of the body where the CT is performed, and does not capture CT charges billed by physicians during the inpatient stay. As a result, it further limited the cases to those with charges for CT to assess if this would impact whether the technology would meet the cost criterion. Per the applicant, it identified 1,546,504 claims mapping to 702 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), which represented 17% of identified cases. The applicant stated that it calculated a final inflated average case-weighted standardized charge per case of $89,176, which exceeded the average case-weighted threshold amount of $71,344.

The applicant asserted that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the Annalise Enterprise CTB Triage—OH meets the cost criterion.

[117] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

Annalise Enterprise CTB Triage - OH COST ANALYSIS[117]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For the lists of ICD-10-CM codes, see the online posting for the Annalise Enterprise CTB Triage - OH.
List of MS-DRGs	For the lists of MS-DRGs and titles, see the online posting for the Annalise Enterprise CTB Triage - OH.
Inclusion/ exclusion criteria	Primary Analysis: The applicant selected claims based on the inclusion of ICD-10-CM codes provided in the online posting that included an ER visit defined as the Emergency Room Charge Amount greater than 0 and/or the inpatient admission type code equal to "1," as it believed this analysis best represented patients for whom the doctor is likely to order the Annalise AI technology to be run to determine if there is any evidence for OH. Analysis 2: The applicant selected claims based on the inclusion of a larger set of ICD-10-CM codes provided in the online posting that included an ER visit defined as the Emergency Room Charge Amount greater than 0 and/or the inpatient admission type code equal to "1". Analysis 3: The applicant applied the inclusion/exclusion criteria used in the primary analysis and identified cases that included charges for a CT scan. Specifically, the applicant only included cases where radiology CT charges were greater than 0 or the Radiology CT Scan Indicator Switch was equal to "1". All case counts for MS-DRGs with less than 11 cases were imputed a value of 11 cases. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant stated that it did not remove charges for a prior technology because the technology is not expected to remove the need for prior technologies or remove the costs associated with prior technologies. The applicant maintained that the Annalise AI technology works in collaboration with NCCT scans to identify patients that are likely to have OH. The applicant did not remove indirect charges related to a prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant calculated an average cost per case by taking the average cost per case across all hospitals studied. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.128 for radiology from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

According to the applicant, the technology is used to aid in the triage and prioritization of studies with features suggestive of OH. However, the diagnosis codes that the applicant used to identify eligible cases included non-neurologic diagnosis codes (for example, U071, R0602, J189). We question whether these diagnosis codes are applicable, and whether using neurologic diagnosis codes for diagnoses that exhibit symptoms similar to OH would more accurately identify eligible cases.

Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and are proposing to approve the Annalise Enterprise CTB Triage—OH for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Annalise Enterprise CTB Triage—OH to the hospital to be $371.37 per patient. According to the applicant, hospitals acquire the Annalise Enterprise CTB Triage—OH system on a subscription-based model, with an annual cost of $180,000 per hospital. The applicant stated that the average cost per patient per hospital will vary by the volume of the NCCT cases for which the software is used. To determine the cost per case, the applicant used the following methodology:

First, the applicant conducted market research to estimate the percent of NCCT cases where this software would likely be ordered, which was estimated at 50% of NCCT head scans for older patients (>65 years of age) and 30% of NCCT head scans for younger patients (<65 years of age).

Second, the applicant used the 2021 SAF LDS to identify total NCCT scans by hospital. To represent the full Medicare fee-for-service population, the applicant multiplied total NCCT head scans at each hospital from the data by 20.

Third, to calculate the total number of NCCT head scans for each hospital, the applicant assumed that 56.5% of all NCCT scans are for Medicare beneficiaries, based on literature on trends in the utilization of head CT scans in the United States.[118]

Fourth, to calculate the cost per case for each hospital, the applicant divided $180,000 by the estimated number of NCCT head scans analyzed by the technology for each hospital. Per the applicant, the average cost per case across all IPPS hospitals was then calculated at $371.37.

The applicant asserted that calculating the cost per case across all IPPS hospitals was reasonable. The applicant noted that given its limited time on the market and low number of subscribers, it used all IPPS hospitals to calculate cost per case rather than

[118] Selfi, A, Jafari, S, and Mirmoeeni, S et al. (June 16, 2022) Trends in inpatient utilization of head computerized tomography scans in the United States: A brief cross-sectional study. *Cureus* 14(6): e26018. DOI 10.7759/cureus.26018

limiting the analysis to current subscribers. The applicant mentioned that for technologies that are commercially available for a longer period of time and with more subscribers, it may make sense to limit the cost per case analysis to hospitals that are current subscribers rather than using all IPPS hospitals in the calculation.

As we noted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630) and in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44983), we understand that there are unique circumstances with respect to determining a cost per case for a technology that utilizes a subscription for its cost and we will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for add-on payment.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Annalise Enterprise CTB Triage—OH would be $241.39 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the Annalise Enterprise CTB Triage—OH meets the cost criterion and our proposal to approve new technology add-on payments for the Annalise Enterprise CTB Triage—OH for FY 2025 for use in the medical care environment to aid in triage and prioritization of studies with features suggestive of OH.

b. ASTar® System

Q-linea submitted an application for new technology add-on payments for the ASTar® System for FY 2025. According to the applicant, the ASTar® System is a fully automated system for rapid antimicrobial susceptibility testing (AST). The applicant stated that the proprietary AST technology is based on broth microdilution (BMD), optimized for high sensitivity and short time-to-result, delivering phenotypic AST with true minimum inhibitory concentration (MIC) results in approximately six hours.

Please refer to the online application posting for the ASTar® System, available at *https://mearis.cms.gov/public/publications/ntap/NTP231013T7Y5F,* for additional detail describing the technology and how it is used.

According to the applicant, the ASTar® System consists of the ASTar® Instrument and the ASTar® BC G-Kit. According to the applicant, the ASTar® Instrument and ASTar® BC G-Kit, which includes the ASTar® BC G-Consumable Kit and the ASTar BC G-Frozen Insert, received Breakthrough Device designation from FDA on April 7, 2022. The ASTar® BC G-Kit is a multiplexed, *in vitro,* diagnostic test utilizing AST methods and is intended for use with the ASTar® Instrument. The ASTar® BC G-Kit is performed directly on positive blood cultures confirmed positive for Gram-negative bacilli only by Gram stain, and tests antimicrobial agents with nonfastidious and fastidious bacterial species. According to the applicant, its marketing authorization request for the ASTar® BC G-Kit has been accepted by FDA, and it anticipates a 510(k) decision from FDA for the same indication consistent with the Breakthrough Device designation before May 1, 2024. The applicant stated that it anticipates the technology will be available on the market immediately after 510(k) clearance from FDA.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the ASTar® System. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the ASTar® System beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the ASTar® System under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. Each analysis used different ICD–10–CM codes to identify potential cases in the FY 2022 MedPAR file representing patients who may be eligible for the ASTar® System. According to the applicant, Cohort 1 comprised patients with non-sepsis infections and Cohort 2 consisted of patients with sepsis resulting from bacteria identifiable by the ASTar® System. The applicant explained that these scenarios were separated as the applicant believed that charges and MS–DRG assignments may differ due to the resources required to treat sepsis patients compared to those required for less severe infections. Finally, Cohort 3 included all ICD–10–CM codes from Cohorts 1 and 2 because the applicant stated that the ASTar® System may be used to identify any infection caused by the bacteria listed in Cohorts 1 and 2. The applicant stated that in all three cohorts, the patients mapped to a large number of MS–DRGs based on the listed ICD–10–CM codes. Therefore, in the analyses, the applicant only included the most common MS–DRGs, that is, the MS–DRGs containing at least 1 percent of the potential case volume within each of the three cohorts, as these are the MS–DRGs to which potential ASTar® System cases would most closely map. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section to identify claims for each cohort. Each analysis followed the order of operations described in the table that follows later in this section.

For Cohort 1, the applicant identified 440,838 claims mapping to 14 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis with MV >96 Hours with MCC) representing 25% of identified cases, and calculated a final inflated average case-weighted standardized charge per case of $85,525, which exceeded the average case-weighted threshold amount of $70,398.

For Cohort2, the applicant identified 224,825 claims mapping to 7 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis with MV >96 Hours with MCC) representing 54% of identified cases, and calculated a final inflated average case-weighted standardized charge per case of $99,508, which exceeded the average case-weighted threshold amount of $82,171.

For Cohort3, the applicant identified 603,877 claims mapping to 13 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis with MV >96 Hours with MCC) representing 34% of identified cases, and calculated a final inflated average case-weighted standardized charge per case of $88,395

[119] Codes referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

which exceeded the average case-weighted threshold amount of $73,727.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all the three cohorts, the applicant asserted that the ASTar® System meets the cost criterion.

ASTar® System COST ANALYSIS[119]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For the lists of ICD-10-CM codes, see the online posting for the ASTar® System.
List of MS-DRGs	For the lists of MS-DRGs and titles, see the online posting for the ASTar® System.
Inclusion/ exclusion criteria	The applicant only included the MS-DRGs containing at least 1 percent of the potential case volume within each of the three cohorts as these are the MS-DRGs to which potential ASTar® System cases would most closely map. Cohort 1: The applicant identified claims using the ICD-10-CM codes provided in the online posting, which it stated represents patients with non-sepsis infections. Cohort 2: The applicant identified claims using the ICD-10-CM codes provided in the online posting, which it stated represents patients with sepsis resulting from the bacteria that can be identified by the ASTar® System. Cohort 3: The applicant included all ICD-10-CM codes from Cohorts 1 and 2 because the applicant stated that the ASTar® System may be used to identify any infection caused by the bacteria listed in Cohorts 1 and 2.
Charges removed for prior technology	The applicant stated that the ASTar® System is expected to replace existing antimicrobial testing for this patient sample. Per the applicant, CPT code 87186 (Susceptibility studies, antimicrobial agent; microdilution or agar dilution (minimum inhibitory concentration [MIC] or breakpoint), each multi-antimicrobial, per plate) is currently used to bill for antimicrobial testing. To understand the charges associated with CPT code 87186, the applicant used the CMS Public Use File "Medicare Physician & Other Practitioners - by Geography and Service" dataset, filtered to 2021 and the national level and noted that Medicare reported charges for CPT code 87186 as $51. The applicant removed this prior technology charge in each analysis. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule and/or correction notice.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.102 for laboratory from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the ASTar® System meets the cost criterion and are therefore proposing to approve the ASTar® System for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the operating cost of the ASTar® System to the hospital to be $150 per patient, based on the operating component ASTar® BC G-Kit (composed of the ASTar® BC G-Consumable Kit ($141) and ASTar BC G-Frozen Insert ($9)). The applicant also noted a capital cost of $200,000 for the ASTar® Instrument. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant stated that the cost of the ASTar® Instrument is a capital cost. Therefore, it appears that this component is not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We note that any new technology add-on payment for the ASTar® System would include only the cost of ASTar® BC G-Kit ($150). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit

[119] Codes referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the ASTar® System would be $97.50 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the ASTar® System meets the cost criterion and our proposal to approve new technology add-on payments for the ASTar® System for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

c. Cefepime-Taniborbactam

Venatorx Pharmaceuticals, Inc. submitted an application for new technology add-on payments for cefepime-taniborbactam for FY 2025. According to the applicant, cefepime-taniborbactam is an investigational β-lactam antibiotic/β-lactamase inhibitor combination under development for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, melioidosis, and hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP).

Please refer to the online application posting for cefepime-taniborbactam, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310168RYEB,* for additional detail describing the technology and the disease treated by the technology.

According to the applicant, cefepime-taniborbactam received QIDP designation from FDA on February 4, 2022, for cUTI, complicated intra-abdominal infections (cIAI), HABP, VABP, and melioidosis. The applicant stated that it is seeking approval from FDA for the treatment of patients 18 years of age and older with cUTI, including pyelonephritis caused by designated susceptible gram-negative bacteria, including cases with concurrent bacteremia. According to the applicant, its marketing request for cefepime-taniborbactam has been filed by FDA, and it anticipates an NDA decision before July 1, 2024. According to the applicant, cefepime-taniborbactam is not expected to be commercially available immediately after FDA approval due to manufacturing readiness activities and the expected commercial availability date is October 1, 2024. We note that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), cefepime-taniborbactam is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2024, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2025), as provided in § 412.87(f)(3). To estimate the average dosage per patient, the applicant calculated a weighted average duration of treatment. Per the applicant, based on the dosing schedule, a patient receives approximately 3 doses per 24 hours. The applicant noted for 48 patients with bacteremia, the average length of stay was 10.9 days, and for 392 patients without bacteremia, the average length of stay was 7.2 days, which led to a weighted average treatment duration of 7.5 days and 23 doses per average inpatient stay.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify cefepime-taniborbactam. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for cefepime-taniborbactam beginning in FY 2025. The applicant stated that ICD–10–CM diagnosis codes for the treatment of cUTI may be used to currently identify the indication for cefepime-taniborbactam under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for cefepime-taniborbactam, the applicant searched the FY 2022 MedPAR file for claims that had one of the ICD–10–CM codes reflecting conditions that would be considered an indication for cefepime-taniborbactam for the treatment of cUTI. Using the inclusion/exclusion criteria described in the following table, the applicant identified 833,530 claims mapping to 526 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC), 690 (Kidney and Urinary Tract Infections without MCC), and 689 (Kidney and Urinary Tract Infections with MCC). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $91,218, which exceeded the average case-weighted threshold amount of $71,256. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that cefepime-taniborbactam meets the cost criterion.

[120] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

CEFEPIME-TANIBORBACTAM COST ANALYSIS[120]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For the list of ICD-10-CM codes included in the cost analysis, see the online posting for cefepime-taniborbactam
List of MS-DRGs	For the list of MS-DRGs included in the cost analysis, see the online posting for cefepime-taniborbactam
Inclusion/exclusion criteria	The applicant identified cases by using the ICD-10-CM codes provided in the online posting in any position on the claim, as it believes these codes reflect conditions that would be considered an indication for cefepime-taniborbactam for the treatment of cUTI. The applicant then excluded MS-DRGs with a case volume fewer than 11 total cases. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant removed 100% of drug charges from cases to estimate the potential decrease in costs due to the use of cefepime-taniborbactam. The applicant did not remove indirect charges related to the prior technology because it believes that cefepime-taniborbactam would not replace any related charges.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.3% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

We agree with the applicant that cefepime-taniborbactam meets the cost criterion and are therefore proposing to approve cefepime-taniborbactam for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a QIDP for the indication corresponding to the QIDP designation by July 1, 2024. As an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), cefepime-taniborbactam is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2024, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2025), as provided in § 412.87(f)(3). If cefepime-taniborbactam receives FDA marketing authorization before July 1, 2025, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2025, no new technology add-on payments would be made for cases involving the use of cefepime-taniborbactam for FY 2025.

The applicant has not provided an estimate for the cost of cefepime-taniborbactam at the time of this proposed rule. Per the applicant, based on the dosing schedule, a patient receives approximately 3 doses per 24 hours. The applicant noted for 48 patients with bacteremia, the average length of stay was 10.9 days, and for 392 patients without bacteremia, the average length of stay was 7.2 days, which led to a weighted average treatment duration of 7.5 days and 23 doses per average inpatient stay. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for cefepime-taniborbactam would be subject to our policy under § 412.88(a)(2)(ii)(B) where we limit new technology add-on payment for QIDPs to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS–DRG payment for the case.

We invite public comments on whether cefepime-taniborbactam meets the cost criterion and our proposal to approve new technology add-on payments for cefepime-taniborbactam for FY 2025, subject to the technology receiving FDA marketing authorization consistent with its QIDP designation by July 1, 2024.

d. Edwards EVOQUE™ Tricuspid Valve Replacement System (Transcatheter Tricuspid Valve Replacement System)

Edwards Lifesciences LLC submitted an application for new technology add-on payments for the Edwards EVOQUE™ Tricuspid Valve Replacement System (''EVOQUE™ System'') for FY 2025. According to the applicant, the EVOQUE™ System is a new, transcatheter treatment option for patients with at least severe tricuspid regurgitation. Per the applicant, the EVOQUE™ System is designed to replace the native tricuspid valve and consists of a transcatheter bioprosthetic valve, a catheter-based delivery system, and supporting accessories.

Please refer to the online application posting for the Edwards EVOQUE™ Tricuspid Valve Replacement System, available at *https://mearis.cms.gov/public/publications/ntap/NTP231013MRRBG,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the EVOQUE™ System received Breakthrough Device designation from FDA on December 18, 2019, for the treatment of patients with symptomatic moderate or above tricuspid regurgitation. The applicant stated that the technology received premarket approval from FDA on February 1, 2024 for a narrower indication for use, for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical

therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team. Since the indication for which the applicant received premarket approval is included within the scope of the Breakthrough Device designation, it appears that the PMA indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. According to the applicant, the EVOQUE™ System was commercially available immediately after FDA approval.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the EVOQUE™ System. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the EVOQUE™ System beginning in FY 2025. The applicant stated that ICD–10–CM diagnosis codes I07.1 (Rheumatic tricuspid insufficiency), I07.2 (Rheumatic tricuspid stenosis and insufficiency), I36.1 (Nonrheumatic tricuspid (valve) insufficiency), and I36.2 (Nonrheumatic tricuspid (valve) stenosis with insufficiency) may be used to currently identify the indication for the EVOQUE™ System under the ICD–10–CM coding system.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that the technology meets the cost criterion. To identify potential cases representing patients who may be eligible for the EVOQUE™ System, each analysis used the same ICD–10–CM diagnosis codes in different positions, with and without selected ICD–10–PCS procedure codes, to identify relevant cases in the FY 2022 MedPAR file. Each analysis followed the order of operations described in the table that follows later in this section.

For the first analysis, the applicant searched for cases assigned to MS–DRGs 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC) and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC) that included one of the four ICD–10–CM diagnosis codes in any position, as listed in the table that follows later in this section. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 2,728 claims mapping to the two MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $267,720, which exceeded the average case-weighted threshold amount of $194,848.

For the second analysis, the applicant searched for the cases that included any of the ICD–10–PCS codes for percutaneous repair or replacement of the tricuspid valve in any position, in combination with one of the four ICD–10–CM codes for tricuspid valve insufficiency as the primary diagnosis, as listed in the table that follows later in this section. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 198 claims mapping to 6 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $327,236, which exceeded the average case-weighted threshold amount of $219,225.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the EVOQUE™ System meets the cost criterion.

EVOQUE™ TRICUSPID VALVE REPLACEMENT SYSTEM COST ANALYSIS	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-PCS codes	Analysis 1: None Analysis 2: 02QJ3ZG (Repair tricuspid valve created from right atrioventricular valve, percutaneous approach) 02QJ3ZZ (Repair tricuspid valve, percutaneous approach) 02RJ37H (Replacement of tricuspid valve with autologous tissue substitute, transapical, percutaneous approach) 02RJ37Z (Replacement of tricuspid valve with autologous tissue substitute, percutaneous approach) 02RJ38H (Replacement of tricuspid valve with zooplastic tissue, transapical, percutaneous approach) 02RJ38Z (Replacement of tricuspid valve with zooplastic tissue, percutaneous approach) 02RJ3JH (Replacement of tricuspid valve with synthetic substitute, transapical, percutaneous approach) 02RJ3JZ (Replacement of tricuspid valve with synthetic substitute, percutaneous approach) 02RJ3KH (Replacement of tricuspid valve with nonautologous tissue substitute, transapical, percutaneous approach) 02RJ3KZ (Replacement of tricuspid valve with nonautologous tissue substitute, percutaneous approach)
List of ICD-10-CM codes	For both analyses: I07.1 (Rheumatic tricuspid insufficiency) I07.2 (Rheumatic tricuspid stenosis and insufficiency) I36.1 (Nonrheumatic tricuspid (valve) insufficiency) I36.2 (Nonrheumatic tricuspid (valve) stenosis with insufficiency)
List of MS-DRGs	Analysis 1: 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC) 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC) Analysis 2: 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC) 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC) 319 (Other Endovascular Cardiac Valve Procedures with MCC) 320 (Other Endovascular Cardiac Valve Procedure without MCC) 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth, and Neck with Major O.R. Procedures) 216 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC)
Inclusion/exclusion criteria	Analysis 1: The applicant searched cases assigned to the two MS-DRGs listed above for selected claims reporting one of the ICD-10-CM codes listed above in any position. Analysis 2: The applicant selected claims reporting one of the ICD-10-CM codes listed above in the primary position in combination with any of the ICD-10-PCS codes listed above.
Charges removed for prior technology	The applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). The applicant noted that use of the EVOQUE™ system is expected to replace a portion of devices included in these claims, although it would not replace all devices, nor any medical supplies required to perform the procedure. However, the applicant could not determine an estimate of the percentage of these total charges for devices that would be replaced. To be as conservative as possible, the applicant removed 100% of these charges.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the preliminary per-patient cost of the technology by the national cost to charge (CCR) ratio of 0.269 for implantable devices from the FY2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology as it stated that no other hospital charges were assumed to be required for implanting the EVOQUE™ System.

We agree with the applicant that the EVOQUE™ System meets the cost criterion and are therefore proposing to approve the EVOQUE™ System for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the EVOQUE™ System to the hospital to be $49,000 per patient, which includes the following components: the EVOQUE™ Tricuspid Delivery System, the EVOQUE™ Dilator Kit, the EVOQUE™ Loading System, the Stabilizer, Base, and Plate, and the EVOQUE™ Valve. The applicant noted that the listed

components of the EVOQUE™ System are sold together as one unit because they are all needed to perform the procedure, are all single patient use, and are not sold separately. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the EVOQUE™ System would be $31,850 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the EVOQUE™ System meets the cost criterion and our proposal to approve new technology add-on payments for the EVOQUE™ System for FY 2025 for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team.

e. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)

W.L. Gore & Associates, Inc. submitted an application for new technology add-on payments for the TAMBE Device for FY 2025. According to the applicant, the TAMBE Device is used for endovascular repair in patients with thoracoabdominal aortic aneurysms (TAAA) and high-surgical risk patients with pararenal abdominal aortic aneurysms (PAAA) who have appropriate anatomy. Per the applicant, the TAMBE Device is comprised of multiple required components, including: (1) an Aortic Component, (2) Branch Components, (3) a Distal Bifurcated Component, and (4) Contralateral Leg Component. According to the applicant, these components together comprise the TAMBE Device.

Please refer to the online application posting for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device), available at *https://mearis.cms.gov/public/publications/ntap/NTP231016DYQQX,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the TAMBE Device received Breakthrough Device designation from FDA on October 1, 2021, for endovascular repair of thoracoabdominal and pararenal aneurysms in the aorta in patients who have appropriate anatomy. According to the applicant, the TAMBE Device received premarket approval (PMA) from FDA on January 12, 2024, for a slightly narrower indication for use, namely, TAAA and high-surgical risk patients with PAAA who have appropriate anatomy. Since the indication for which the applicant received premarket approval is included within the scope of the Breakthrough Device designation, it appears that the PMA indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. According to the applicant, the TAMBE Device is not yet available for sale due to the required lead time to train physicians on the TAMBE Device, and the first commercial device will only be implanted May 1, 2024 or later. We are interested in additional information regarding the delay in the technology's market availability, as we question whether the date the device first became available for sale would be the same as the date the first commercial device is implanted.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the TAMBE Device. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the TAMBE Device beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the proposed indication for the TAMBE Device under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the TAMBE Device, the applicant searched the FY 2022 MedPAR file for claims that had at least one of the ICD–10–CM codes and at least one of the ICD–10–PCS codes as listed in the following table. Using the inclusion/exclusion criteria described in the following table, the applicant identified 1,005 claims mapping to 19 MS–DRGs, including MS–DRG 269 (Aortic and Heart Assist Procedures except Pulsation Balloon without MCC), which represented 54.5% of the identified cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $448,347, which exceeded the average case-weighted threshold amount of $185,799. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the TAMBE Device meets the cost criterion.

[121] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

TAMBE Device COST ANALYSIS[121]	
Data Source and Time Period	FY 2022 MedPAR file
List ICD-10-PCS codes	04V03FZ (Restriction of abdominal aorta with branched or fenestrated intraluminal device, three or more arteries, percutaneous approach) 04V04FZ (Restriction of abdominal aorta with branched or fenestrated intraluminal device, three or more arteries, percutaneous endoscopic approach)
List of ICD-10-CM codes	I71.4 (Abdominal aortic aneurysm, without rupture) I71.6 (Thoracoabdominal aortic aneurysm, without rupture)
List of MS-DRGs	For the list of MS-DRGs, see the online posting for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device).
Inclusion/exclusion criteria	The applicant stated that it identified cases using the ICD-10-CM codes listed in this table in conjunction with the presence of one of the ICD-10-PCS codes specified in this table. Per the applicant, this combination was considered indicative of the off-label TAAA and PAAA physician-modified endograft (PMEG) cases, which, according to the applicant, reasonably approximated the cost of the TAMBE Device once all the current implantable device charges are removed and replaced with charges for the TAMBE Device. The applicant noted that it calculated the average unstandardized charge per case for each MS-DRG using only covered departmental charges used by CMS for rate-setting. Per the applicant, charges for organ acquisition, managed care cases, claims submitted only for graduate medical education payments, claims with ancillary costs of zero, and claims that were statistical outliers within the MS-DRG were excluded.
Charges removed for prior technology	Per the applicant, the use of the TAMBE Device would replace any ad hoc, off-label PMEGs for which charges are assigned to the implant category. The applicant stated that it used a conservative approach and removed all implant charges. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2024 IPPS/LTCH PPS final rule and the GAF from the Impact File in the FY 2022 final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant determined the number and types of components that were used for an average patient based on the pivotal clinical trial and calculated the case cost per component. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.269 for implantable devices from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the TAMBE Device meets the cost criterion and are therefore proposing to approve the TAMBE Device for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the TAMBE Device to the hospital to be $72,675 per patient. Per the applicant, the TAMBE Device has a number of required components, including the aortic component ($29,000), branch components ($3,355), distal bifurcated component (DBC) ($10,758), DBC extender component ($3,037), contralateral leg endoprosthesis ($4,390), and iliac extender endoprosthesis ($3,037). The applicant stated that the actual type and number of components used varies by patient depending on their anatomy and the extent of the patient's aneurysm. The applicant determined the number and types of components that were used in an average patient based on a multicenter pivotal clinical trial conducted predominantly in the U.S. and calculated the case cost per component. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the TAMBE Device would be $47,238.75 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the TAMBE Device meets the cost criterion and our proposal to approve new technology add-on payments for the TAMBE Device for FY 2025, for endovascular repair in patients with thoracoabdominal aortic aneurysms and high-surgical risk patients with pararenal aortic aneurysms who have appropriate anatomy.

f. LimFlow™ System

LimFlow Inc. submitted an application for new technology add-on payments for the LimFlow™ System for FY 2025. According to the applicant, the LimFlow™ System is a single-use, medical device system designed to treat patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. Per the applicant, the LimFlow™ System consists of LimFlow's Cylindrical and Conical Stent Grafts that are used in conjunction with a LimFlow™ Arterial Catheter, a LimFlow™ Venous Catheter, and a LimFlow™ Valvulotome. According to

the applicant, the LimFlow™ System is used for transcatheter arterialization of the deep veins, a minimally invasive procedure that aims to restore blood flow to the ischemic foot by diverting a stream of oxygenated blood through tibial veins in order to permanently bypass heavily calcified and severely stenotic arteries defined as unreconstructable. We note that LimFlow Inc. submitted an application for new technology add-on payments for the LimFlow™ System for FY 2024 as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26938 through 26940), but the technology did not meet the applicable deadline of July 1, 2023 for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2024 (88 FR 58919).

Please refer to the online application posting for the LimFlow™ System, available at *https://mearis.cms.gov/public/publications/ntap/NTP23101627LXC,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the LimFlow™ System received Breakthrough Device designation from FDA on October 3, 2017, for the treatment of critical limb ischemia by minimally invasively creating an arterio-venous bypass graft to produce the venous arterialization procedure in the below-the-knee vasculature. The applicant stated that the technology was granted premarket approval from FDA on September 11, 2023, for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. Since the indication for which the applicant received premarket approval is considered equivalent to the Breakthrough Device designation, it appears that the premarket approval indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. Per the applicant, the LimFlow™ System was not immediately available for sale because inventory build and ramp for commercial sales was set to commence following FDA approval to allow time for the conduct of surgeon training and medical education on patient selection, indications, and surgical technique. The applicant stated that the technology became commercially available on November 1, 2023.

The applicant provided a list of ICD–10–PCS codes that, effective October 1, 2018, can be used to uniquely describe procedures involving the use of the LimFlow™ System under the ICD–10–PCS coding system. Please see the online posting for the LimFlow™ System for the complete list of ICD–10–PCS codes provided by the applicant. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the LimFlow™ System under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided three analyses to demonstrate that it meets the cost criterion. Each analysis used the same ICD–10–PCS codes to identify potential cases representing patients who may be eligible for the LimFlow™ System. The applicant stated that the selected claims represent the exact situations in which the LimFlow™ System would be used and represent the cost of care associated with the use of the LimFlow™ System. The applicant utilized a different year of MedPAR data in each analysis. According to the applicant, it used multiple years of data because the case count in each individual year was low. The applicant imputed a value of 11 cases for MS–DRGs with less than 11 cases. Each analysis followed the order of operations described in the table that follows later in this section.

For the first analysis, the applicant searched FY 2022 MedPAR data for claims reporting at least one of the ICD–10–PCS codes listed in the table that follows later in this section to identify cases that may be eligible for the LimFlow™ System. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 88 claims mapping to 8 MS–DRGs, with none exceeding more than 13% of the total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $307,461 which exceeded the average case-weighted threshold amount of $124,971.

For the second analysis, the applicant searched FY 2021 MedPAR data for claims reporting at least one of the ICD–10–PCS codes listed in the table that follows later in this section to identify cases that may be eligible for the LimFlow™ System. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 111 claims mapping to 10 MS–DRGs, with none exceeding more than 11% of the total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $277,454, which exceeded the average case-weighted threshold amount of $116,278.

For the third analysis, the applicant searched FY 2020 MedPAR data for claims reporting at least one of the ICD–10–PCS codes listed in the table that follows later in this section to identify cases that may be eligible for the LimFlow™ System. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 99 claims mapping to 9 MS–DRGs, with none exceeding more than 12% of the total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $273,638 which exceeded the average case-weighted threshold amount of $125,153.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the LimFlow™ System meets the cost criterion.

[122] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

LimFlow™ System COST ANALYSIS[122]	
Data Source and Time Period	Analysis 1: FY 2022 MedPAR file Analysis 2: FY 2021 MedPAR file Analysis 3: FY 2020 MedPAR file
List of ICD-10-PCS codes	041M3JS (Bypass right popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041N3JS (Bypass left popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041P3JS (Bypass right anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041Q3JS (Bypass left anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041R3JS (Bypass right posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041S3JS (Bypass left posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041T3JS (Bypass right peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041U3JS (Bypass left peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach)
List of MS-DRGs	For the lists of MS-DRGs for the three analyses, see the online posting for the LimFlow™ System
Inclusion/ exclusion criteria	For all three analyses, the applicant selected claims using the ICD-10-PCS codes listed in this table Each scenario utilized a different year of MedPAR data. The resulting MS-DRGs associated with identified cases are provided in the online posting. The applicant included only claims that would be used for rate setting (fee-for-service IPPS discharges, plus Maryland hospital discharges). The applicant imputed 11 cases for all DRGs where the case count was fewer than 11.
Charges removed for prior technology	The applicant used a conservative approach and removed all implantable device charges. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	For Analysis 1 with FY 2022 MedPAR data, the applicant applied an inflation factor of 11.9% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule. For Analysis 2 with FY 2021 MedPAR data, the applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule. For Analysis 3 with FY 2020 MedPAR data, the applicant applied an inflation factor of 25.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.269 for implantable devices from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the LimFlow™ System meets the cost criterion and are therefore proposing to approve the LimFlow™ System for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the LimFlow™ System to the hospital to be $25,000 per patient. According to the applicant, the LimFlow™ System is sold as a system, as such, the components of the LimFlow™ System are not priced or sold to hospitals independently. The applicant stated that all components of the LimFlow™ System are single-use and the entire system is an operating cost. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the LimFlow™ System would be $16,250 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the LimFlow™ System meets the cost criterion and our proposal to approve new technology add-on payments for the LimFlow™ System for FY 2025 for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation.

g. Paradise™ Ultrasound Renal Denervation System

ReCor Medical submitted an application for new technology add-on

payments for the Paradise™ Ultrasound Renal Denervation System for FY 2025. According to the applicant, the Paradise™ Ultrasound Renal Denervation System is an endovascular catheter-based system that delivers SonoWave360™ ultrasound energy circumferentially, thermally ablating and disrupting overactive renal sympathetic nerves to lower blood pressure in adult (≥22 years of age) patients with uncontrolled hypertension who may be inadequately responsive to or who are intolerant to anti-hypertensive medications.

Please refer to the online application posting for the Paradise™ Ultrasound Renal Denervation System, available at *https://mearis.cms.gov/public/publications/ntap/NTP23101772HBQ,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the Paradise™ Ultrasound Renal Denervation System received Breakthrough Device designation from FDA on December 4, 2020, for reducing blood pressure in adult (≥22 years of age) patients with uncontrolled hypertension, who may be inadequately responsive to, or who are intolerant to anti-hypertensive medications. The applicant received FDA premarket approval for the technology on November 7, 2023, for reducing blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Because we consider the indication for which the applicant received premarket approval to be within the scope of the Breakthrough Device designation, and FDA considers this marketing authorization to be for the Breakthrough Device designation,[123] it appears that the premarket approval indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. According to the applicant, the technology was commercially available immediately after FDA approval.

The applicant stated that effective October 1, 2023, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of the Paradise™ Ultrasound Renal Denervation System: X051329 (Destruction of renal sympathetic nerve(s) using ultrasound ablation, percutaneous approach, new technology group 9). The applicant stated that ICD–10–CM codes I10 (Essential (primary) hypertension), I15.1 (Hypertension secondary to other renal disorders), I15.8 (Other secondary hypertension), I15.9 (Secondary hypertension, unspecified), and I1A.0 (Resistant hypertension) may be used to currently identify the indication for the Paradise™ Ultrasound Renal Denervation System under the ICD–10–CM coding system.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. Each analysis used different MS–DRGs and/or ICD–10–CM codes to identify potential cases representing patients who may be eligible for the Paradise™ Ultrasound Renal Denervation System. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the table that follows later in this section.

For the first analysis, the applicant searched the FY 2022 MedPAR file for all cases that map to MS–DRG 264 (Other Circulatory System O.R. Procedures). The applicant stated that medical MS–DRGs 304 and 305 (Hypertension with MCC and without MCC) are specific to hypertension. However, given the nature of the procedure, the applicant's expectation is that the DRG Grouper logic would assign potential cases representing patients who may be eligible for the Paradise™ Ultrasound Renal Denervation System to a surgical MS–DRG. To identify the surgical MS–DRG, the applicant identified ICD–10–PCS code 015M3ZZ (Destruction of abdominal sympathetic nerve, percutaneous approach) as the procedure most similar to the procedure performed using the Paradise™ Ultrasound Renal Denervation System, and determined the specific MS–DRG to which that ICD–10–PCS code maps. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 7,064 claims mapping to MS–DRG 264 (Other Circulatory System O.R. Procedures) and calculated a final inflated average case-weighted standardized charge per case of $357,807, which exceeded the average case-weighted threshold amount of $98,708.

For the second analysis, as a sensitivity analysis the applicant searched the FY 2022 MedPAR file for all cases that map to MS–DRGs 304 or 305 (Hypertension with MCC and without MCC), which are specific to hypertension. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 32,433 claims mapping to MS–DRG 304 (Hypertension with MCC) or 305 (Hypertension without MCC) and calculated a final inflated average case-weighted standardized charge per case of $268,298, which exceeded the average case-weighted threshold amount of $46,986.

For the third analysis, the applicant provided a sensitivity analysis that combined the first and second scenario together for a broader list of MS–DRGs. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 39,497 claims mapping to MS–DRGs 264 (Other Circulatory System O.R. Procedures), 304 (Hypertension with MCC), or 305 (Hypertension without MCC) and calculated a final inflated average case-weighted standardized charge per case of $284,306, which exceeded the average case-weighted threshold amount of $56,237.

For the fourth analysis, the applicant performed a sensitivity analysis to subset the cases assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures) to those reporting the following ICD–10–CM codes: I10 (Essential (primary) hypertension), I15.1 (Hypertension secondary to other renal disorders), I15.8 (Other secondary hypertension), or I15.9 (Secondary hypertension, unspecified) in any position. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 1,477 claims mapping to MS–DRG 264 (Other Circulatory System O.R. Procedures) and calculated a final inflated average case-weighted standardized charge per case of $325,810, which exceeded the average case-weighted threshold amount of $98,708.

For the fifth analysis, the applicant performed a sensitivity analysis to subset the cases assigned to MS–DRGs 264 (Other Circulatory System O.R. Procedures), 304 (Hypertension with MCC), or 305 (Hypertension without MCC) to those reporting the following ICD–10–CM codes: I10 (Essential (primary) hypertension), I15.1 (Hypertension secondary to other renal disorders), I15.8 (Other secondary hypertension), or I15.9 (Secondary hypertension, unspecified) in any position. The applicant used the inclusion/exclusion criteria described in the table that follows later in this

[123] List of Breakthrough Devices with Marketing Authorization: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

section. Under this analysis, the applicant identified 14,415 claims mapping to MS–DRGs 264 (Other Circulatory System O.R. Procedures), 304 (Hypertension with MCC), or 305 (Hypertension without MCC) and calculated a final inflated average case-weighted standardized charge per case of $272,701, which exceeded the average case-weighted threshold amount of $50,817.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all analyses, the applicant asserted that the Paradise™ Ultrasound Renal Denervation System meets the cost criterion.

Paradise™ Ultrasound Renal Denervation System COST ANALYSIS[124]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	Analysis 1-3: Not applicable. Analysis 4-5: I10 Essential (primary) hypertension I15.1 Hypertension secondary to other renal disorders I15.8 Other secondary hypertension I15.9 Secondary hypertension, unspecified
List of ICD-10-PCS codes	Analysis 1: The applicant used 015M3ZZ (Destruction of abdominal sympathetic nerve, percutaneous approach) to identify the MS-DRG upon which the analysis was based. Analysis 2, 3, and 4: Not applicable
List of MS-DRGs	Analyses 1 and 4: 264 Other Circulatory System O.R. Procedures Analysis 2: 304 Hypertension with MCC 305 Hypertension without MCC Analyses 3 and 5: 264 Other Circulatory System O.R. Procedures 304 Hypertension with MCC 305 Hypertension without MCC
Inclusion/ exclusion criteria	Analysis 1: The applicant identified all cases within MS-DRG 264. Analysis 2: The applicant identified all cases within MS-DRGs 304 and 305 as a sensitivity analysis. Analysis 3: The applicant identified all cases within MS-DRGs 264, 304, and 305 as a sensitivity analysis. Analysis 4: The applicant subset cases from analysis 1 to include cases reporting at least one ICD-10-CM code listed in this table in any position as a sensitivity analysis. Analysis 5: The applicant subset cases from analysis 3 to include cases reporting at least one ICD-10-CM code listed in this table in any position as a sensitivity analysis.
Charges removed for prior technology	According to the applicant, the Paradise™ Ultrasound Renal Denervation System is not expected to replace prior technologies. Therefore, no direct or indirect charges associated with prior technologies were removed.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	According to the applicant, the cost of the new technology was determined based on the inputs for furnishing the service for the single-use components. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.102 for cardiac catheterization from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

[124] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

We agree with the applicant that the Paradise™ Ultrasound Renal Denervation System meets the cost criterion and are therefore proposing to approve the Paradise™ Ultrasound Renal Denervation System for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Paradise™ Ultrasound Renal Denervation System to the hospital to be $23,000 per patient, based on single-use components including the operating costs of the catheter kit ($22,000), cable ($250), and cartridge ($750). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Paradise™ Ultrasound Renal Denervation System would be $14,950 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the Paradise™ Ultrasound Renal Denervation System meets the cost criterion and our proposal to approve new technology add-on payments for the Paradise™ Ultrasound Renal Denervation System for FY 2025 for reducing blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure, which corresponds to the Breakthrough Device designation.

h. PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter

Medtronic, Inc. submitted an application for new technology add-on payments for the PulseSelect™ PFA Loop Catheter for FY 2025. According to the applicant, the PulseSelect™ PFA Loop Catheter is used to perform pulmonary vein isolation in cardiac catheter ablation to treat atrial fibrillation. Per the applicant, unlike existing methods that rely on thermal energy (either radiofrequency or cryoablation), PulseSelect™ employs non-thermal irreversible electroporation to induce cell death in cardiac tissue at the target site. According to the applicant, PulseSelect™ technology's non-thermal approach can avoid risks associated with existing thermal cardiac catheter ablation technologies.

Please refer to the online application posting for the PulseSelect™ PFA Loop Catheter, available at *https://mearis.cms.gov/public/publications/ntap/NTP231017BMQKQ,* for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the PulseSelect™ PFA System, which includes a compatible Medtronic multi-electrode cardiac ablation catheter (the PulseSelect™ PFA Loop Catheter), received Breakthrough Device designation from FDA on September 27, 2018, for the treatment of drug refractory recurrent symptomatic atrial fibrillation. The Medtronic multi-electrode cardiac ablation catheter is also intended to be used for cardiac electrophysiological (EP) mapping and measuring of intracardiac electrograms, delivery of diagnostic pacing stimuli and verifying electrical isolation post-treatment. According to the applicant, the PulseSelect™ PFA System received premarket approval on December 13, 2023 for the following indication that reflects a slightly narrower patient population compared to the Breakthrough Device designation: for cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year). The applicant noted that the PulseSelect™ PFA System consists of two primary elements: the PulseSelect™ PFA Loop Catheter and the PulseSelect™ PFA Generator system, but that as capital equipment, the PulseSelect™ PFA Generator system is not the subject of this new technology add-on payment application. According to the applicant, the technology was commercially available immediately after FDA approval.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the PulseSelect™ PFA System and was granted approval for the following procedure code effective April 1, 2024: 02583ZF (Destruction of conduction mechanism using irreversible electroporation, percutaneous approach). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the PulseSelect™ PFA Loop Catheter under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. The applicant stated that there is an expectation the PulseSelect™ PFA Loop Catheter will predominantly be used when both indicated uses are employed in a single patient case. Each analysis used different ICD–10–CM codes to identify potential cases representing patients who may be eligible for the PulseSelect™ PFA Loop Catheter. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the table that follows later in this section.

For the first analysis, the applicant searched the FY 2022 MedPAR file for claims that had the ICD–10–PCS code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) in any procedure code position on the claim and identified 98 MS–DRGs. The applicant limited the cost analysis to the top six MS–DRGs that had over 2% of cases in each MS–DRG (see the table that follows later in this section for a complete list of MS–DRGs provided by the applicant). According to the applicant, these six MS–DRGs represented 86% of all cardiac catheter ablation cases. Using the inclusion/exclusion criteria described in the table that follows later in this section, the applicant identified 14,695 claims mapping to these 6 MS–DRGs. The applicant followed the order of operations described in the table that follows later in this section and calculated a final inflated average case-weighted standardized charge per case of $176,942, which exceeded the average case-weighted threshold amount of $136,813.

For the second analysis, the applicant searched the FY 2022 MedPAR file for claims that had the ICD–10–PCS code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) in any procedure code position on the claim, and had one of the ICD–10–CM codes for atrial fibrillation listed in the table that follows later in this section. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 12,088 claims mapping to the top six MS–DRGs (representing 82.3% of all cases) and calculated a final inflated average case-weighted standardized charge per case of $179,931, which exceeded the average case-weighted threshold amount of $136,782.

For the third analysis, the applicant searched the FY 2022 MedPAR file for claims that had the ICD–10–PCS code 02583ZZ (Destruction of conduction mechanism, percutaneous approach) in

any procedure code position on the claim and had one of the ICD–10–CM codes for paroxysmal or persistent atrial fibrillation listed in the table that follows later in this section. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 9,446 claims mapping to the top six MS–DRGs (representing 64.3% of all cases) and calculated a final inflated average case-weighted standardized charge per case of $180,114, which exceeded the average case-weighted threshold amount of $136,193.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the PulseSelect™ PFA Loop Catheter meets the cost criterion.

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[125] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

PULSESELECT™ PFA LOOP CATHETER COST ANALYSIS[125]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	Analysis 1: not applicable Analysis 2: I48.0 (Paroxysmal atrial fibrillation) I48.11 (Longstanding persistent atrial fibrillation) I48.19 (Other persistent atrial fibrillation) I48.20 (Chronic atrial fibrillation, unspecified) I48.21 (Permanent atrial fibrillation) I48.91 (Unspecified atrial fibrillation) Analysis 3: I48.0 (Paroxysmal atrial fibrillation) I48.11 (Longstanding persistent atrial fibrillation) I48.19 (Other persistent atrial fibrillation)
List of ICD-10-PCS codes	02583ZZ (Destruction of conduction mechanism, percutaneous approach) in any position
List of MS-DRGs	For all analyses: 274 (Percutaneous and Other Intracardiac Procedures without MCC) 273 (Percutaneous and Other Intracardiac Procedures with MCC) 242 (Permanent Cardiac Pacemaker Implant with MCC) 243 (Permanent Cardiac Pacemaker Implant with CC) 229 (Other Cardiothoracic Procedures without MCC) 228 (Other Cardiothoracic Procedures with MCC)
Inclusion/exclusion criteria	Analysis 1: The applicant identified cases by using the ICD-10-PCS code in this table in any procedure code position on the claim. The applicant then limited the analysis to cases that were mapped to the top six MS-DRGs (representing 86% of all cardiac catheter ablation cases). Analysis 2: The applicant identified cases by using the ICD-10-PCS code in this table in any procedure code position on the claim and the ICD-10-CM codes in this table. The applicant limited the analysis to only atrial fibrillation ICD-10-CM diagnosis codes as described in the Breakthrough Device designation indication. The applicant limited the analysis to the top six MS-DRGs (representing 82.3% of all cases). Analysis 3: The applicant identified cases by using the ICD-10-PCS code in this table in any procedure code position on the claim and the ICD-10-CM codes in this table. The applicant limited the analysis to paroxysmal and persistent atrial fibrillation ICD-10-CM diagnosis codes as aligned with the slightly narrower patient population reflected in the final Premarket Approval Application indication. The applicant limited the analysis to the top six MS-DRGs (representing 64.3% of all cases). For each analysis, cases with outlier payments were excluded.
Charges removed for prior technology	Per the applicant, PulseSelect™ will replace currently approved cardiac catheter ablation technologies. The applicant removed 100% of medical surgical supply charges from the identified cases. The applicant stated that this was likely an overestimate of replaced charges as other catheters, sheaths, and supplies will still be used in the PulseSelect™ procedure. While some of the charges associated with these catheters may also be present in the implantable device cost center, depending on individual hospital charging practices, the applicant noted that based on the MS-DRGs identified, other technology charges that are not replaced (for example, pacemakers) would also be reflected in the implantable device cost center. Therefore, the applicant removed the charges associated with supplies but did not remove the charges associated with implantable devices. The applicant stated that this was a conservative, balanced approach intended to not overstate the charges associated with the technology being replaced. The applicant did not remove indirect charges related to the prior technology as it stated that the encounters would only differ in terms of the type of catheter used.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.303 for supplies and equipment from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

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We agree with the applicant that the PulseSelect™ PFA Loop Catheter meets the cost criterion and are therefore proposing to approve the PulseSelect™

PFA Loop Catheter for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the cost of the PulseSelect™ PFA Loop Catheter to the hospital to be $9,750 per patient, and for the PulseSelect™ PFA Catheter Interface Cable to be $800 per patient, totaling $10,550 per inpatient stay. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. We note that the applicant stated that the PulseSelect™ Pulsed Field Ablation (PFA) Interface Cable is listed as a component of the PulseSelect™ Pulsed Field Ablation (PFA) Generator Reusable Accessories. However, we note the submitted new technology add-on payment application is for the PulseSelect™ PFA Loop Catheter, and that the applicant had specified in its application that the PulseSelect™ PFA Generator System is not the subject of this new technology add-on payment application. Therefore, we believe the total cost per inpatient stay should be based only on the cost of the PulseSelect™ PFA Loop Catheter, which is $9,750 per the applicant. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the PulseSelect™ PFA Loop Catheter would be $6,337.50 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the PulseSelect™ PFA Loop Catheter meets the cost criterion and our proposal to approve new technology add-on payments for the PulseSelect™ PFA Loop Catheter for FY 2025 for cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year).

i. Restor3d TIDAL™ Fusion Cage

Restor3d submitted an application for new technology add-on payments for the restor3d TIDAL™ Fusion Cage for FY 2025. According to the applicant, the TIDAL™ Fusion Cages are porous cages that vary in shape and size to accommodate individual patient anatomy. Per the applicant, the TIDAL™ Fusion Cage is comprised of a single, continuous piece of titanium alloy fabricated by laser powder bed fusion, an additive manufacturing technology. According to the applicant, the TIDAL™ Fusion Cage is an accessory to the intramedullary nail for TTC Fusion and has a central clearance hole to contain the intramedullary nail. Per the applicant, the restor3d TIDAL™ Fusion Cage can be used to aid in healing for fractures, bone voids, absent bone, or surgical resections in conjunction with an intramedullary nail for TTC fusion. The applicant noted that the restor3d TIDAL™ Fusion Cages also serve to support and contain bone graft materials that aid in arthrodesis.

Please refer to the online application posting for the restor3d TIDAL™ Fusion Cage, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310167MCW9,* for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the restor3d TIDAL™ Fusion Cage System received Breakthrough Device designation from FDA on June 26, 2023 for the indication of tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures such as: post-traumatic and degenerative arthritis; post-traumatic or primary arthrosis involving both ankle and subtalar joints; revision after failed ankle arthrodesis with subtalar involvement; failed total ankle arthroplasty; non-union ankle arthrodesis; rheumatoid hindfoot; talectomy; avascular necrosis of the talus; neuroarthropathy; neuromuscular disease and severe deformity; osteoarthritis; Charcot foot; and previously infected arthrosis, second degree. The restor3d Fusion Cage System is intended to provide stabilization in long bones of skeletally mature patients, including tibia, femur and humerus, in the presence of critical sized bone defects in lieu of bulk allograft, bone transport or other treatment for segmental defects in procedures such as: stabilization of fractures of the diaphyseal or metaphyseal regions of long bones; malunions and nonunion; osteomyelitis; periprosthetic fractures. According to the applicant, its marketing authorization request for the restor3d TIDAL™ Fusion Cage System has been accepted by FDA, and it anticipates a 510(k) decision from FDA for the same indication consistent with the Breakthrough Device designation before May 1, 2024. The applicant anticipates that the technology will be commercially available immediately after 510(k) clearance from FDA.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the restor3d TIDAL™ Fusion Cage. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the restor3d TIDAL™ Fusion Cage beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the restor3d TIDAL™ Fusion Cage under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the restor3d TIDAL™ Fusion Cage, the applicant searched the FY 2022 MedPAR file for claims that had one of the ICD–10–PCS codes corresponding to fusion procedures or claims that had one of the other ICD–10–PCS codes in combination with one of the selected admitting diagnosis ICD–10–CM codes. According to the applicant, the selected claims represented potential candidates for the technology, who have undergone tibiotalocalcaneal arthrodesis (fusion) and require stabilization of the hindfoot and ankle due to a critical size bone defect. Using the inclusion/exclusion criteria described in the following table, the applicant identified 14,247 claims mapping to 24 MS–DRGs, including MS–DRG 617 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC) and MS–DRG 853 (Infectious and Parasitic Diseases with O.R. Procedures with MCC), each representing 16% of the identified cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $303,575, which exceeded the average case-weighted threshold amount of $109,972.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the restor3d TIDAL™ Fusion Cage meets the cost criterion.

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RESTOR3D TIDAL™ FUSION CAGE COST ANALYSIS[126]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-PCS codes	For the list of ICD-10-PCS codes, see the online posting for the restor3d TIDAL™ Fusion Cage
List of ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for the restor3d TIDAL™ Fusion Cage
List of MS-DRGs	For the list of MS-DRGs, see the online posting for the restor3d TIDAL™ Fusion Cage
Inclusion/exclusion criteria	The applicant identified cases with one of the ICD-10-PCS codes corresponding to fusion procedures, or cases that had one of the other ICD-10-PCS codes in combination with one of the selected admitting diagnosis ICD-10-CM codes from the list of ICD-10-CM/PCS codes provided in the online posting. The applicant believed these cases represented patients who have undergone tibiotalocalcaneal arthrodesis (fusion) and require stabilization of the hindfoot and ankle due to a critical size bone defect, and that these patients, rather than opting for bulk allograft procedures, would be candidates for the use of this technology. The applicant then sorted these cases by MS-DRG, and only included MS-DRGs that had more than 100 cases.
Charges removed for prior technology	The applicant used market intelligence data and the CMS Public Data file to estimate the cost of the technology being replaced. The applicant inflated these costs to hospital level charges using the national average cost-to-charge ratio of 0.269 for implantable devices from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied the 3-year charge inflation factor of 18.4% from the outlier threshold determination in the FY 2024 IPPS final rule to inflate the current case level charges from FY 2022 to FY 2025.
Charges added for the new technology	The applicant used the market intelligence data to estimate the cost related to the restor3d TIDAL™ Fusion Cage. The applicant added charges and indirect charges for the new technology by dividing the cost and the related cost of the new technology by the national average cost-to-charge ratio of 0.269 for implantable devices from the FY 2024 IPPS/LTCH PPS final rule.

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We agree with the applicant that the restor3d TIDAL™ Fusion Cage meets the cost criterion and are therefore proposing to approve the restor3d TIDAL™ Fusion Cage for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the cost of the restor3d TIDAL™ Fusion Cage for each patient to be $27,995. In addition, the applicant noted the costs related to the technology for required supporting instruments and materials consist of one unit each of the Instrument Kit ($6,995), TTC Fusion Nail ($7,500), and Bone Graft ($1,500). The applicant estimated the total cost to the hospital to be $43,990 for each procedure per patient, including the related cost of the technology. As we have discussed in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device (86 FR 45146). Based on the information provided by the applicant, the cost of the Instrument Kit is included in the costs of the supporting instruments and materials for each procedure related to the use of the technology, rather than a cost of the technology itself. In addition, the TTC Fusion Nail and Bone Graft are not new and unique components for this technology, and can be purchased separately in support of other technologies. Furthermore, we note that the Instrument Kit is not included in the Breakthrough Device designation, and it therefore appears that only the restor3d TIDAL™ Fusion Cage would be designated as the Breakthrough Device once market authorized and would be eligible for new technology add-on payments under the alternative pathway. Therefore, it appears any add-on payment for the restor3d TIDAL™ Fusion Cage would include only the cost of the restor3d TIDAL™ Fusion Cage ($27,995).

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the restor3d TIDAL™ Fusion Cage would be $18,196.75 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the restor3d TIDAL™ Fusion Cage meets the cost criterion and our proposal to approve new technology add-on payments for the restor3d TIDAL™ Fusion Cage for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

[126] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

j. Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter

Medtronic submitted an application for new technology add-on payments for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter for FY 2025. According to the applicant, the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter provides a treatment option for patients with uncontrolled hypertension, when used with the Symplicity G3™ Generator, by delivering targeted radiofrequency energy to the renal nerves, safely disrupting overactive sympathetic signaling between the kidneys and brain, as a treatment for uncontrolled hypertension.

Please refer to the online application posting for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310161U617,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the Symplicity Spyral™ Multi-Electrode Renal Denervation System received Breakthrough Device designation from FDA on March 27, 2020, for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients who may have documented intolerance to anti-hypertensive medications. The applicant received premarket approval for the technology on November 17, 2023, for reducing blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. Because we consider the indication for which the applicant received premarket approval to be within the scope of the Breakthrough Device designation, and FDA considers this marketing authorization to be for the Breakthrough Device,[127] it appears that the premarket approval indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. According to the applicant, the technology was commercially available immediately after FDA approval.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided two analyses and two sensitivity analyses to demonstrate that it meets the cost criterion. Each analysis used a common set of ICD–10–CM codes but different criteria for the inclusion/exclusion of MS–DRGs and outlier cases to identify potential cases representing patients who may be eligible for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the table that follows later in this section.

For the first scenario (Cost Analysis #1), the applicant searched the FY 2022 MedPAR file for cases where essential (primary) hypertension was the reason for the admission, using at least one of the ICD–10–CM diagnosis codes in the table that follows later in this section. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 490,387 claims mapping to 99 MS–DRGs, including MS–DRG 291 (Heart Failure and Shock With MCC) representing 67% of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $136,450, which exceeded the average case-weighted threshold amount of $62,312.

The second scenario (Cost Analysis #1 with Outliers) was a sensitivity analysis that mirrored the first scenario, except that cases with outlier payments were included. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 501,760 claims mapping to 101 MS–DRGs, including MS–DRG 291 (Heart Failure and Shock With MCC) representing 66.7% of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $145,001, which exceeded the average case-weighted threshold amount of $63,789.

For the third scenario (Cost Analysis #2), the applicant searched the FY 2022 MedPAR file for claims reporting any of the ICD–10–CM diagnosis codes listed in the table that follows later in this section but limited the case selection to MS–DRGs where the principal diagnosis was essential hypertension, and no procedures were performed. Per the applicant, this list represents a subset of cases that were most likely to benefit from the new procedural treatment option for primary hypertension. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 390,384 claims mapping to 8 MS–DRGs, including MS–DRG 291 (Heart Failure and Shock With MCC) representing 84.4% of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $124,525, which exceeded the average case-weighted threshold amount of $52,861.

The fourth scenario (Cost Analysis #2 with Outliers) mirrored the third scenario, except that cases with outlier payments were included. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 395,634 claims mapping to 8 MS–DRGs, including MS–DRG 291 (Heart Failure and Shock With MCC) representing 84.5% of identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $128,356, which exceeded the average case-weighted threshold amount of $52,873.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter meets the cost criterion.

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[127] List of Breakthrough Devices with Marketing Authorization: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

[128] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter COST ANALYSIS[128]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For all scenarios: I10 Essential (primary) hypertension I11.0 Hypertensive heart disease with heart failure I11.9 Hypertensive heart disease without heart failure I12.0 Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease I12.9 Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease I13.0 Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease I13.10 Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease I13.11 Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease I13.2 Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease I16.0 Hypertensive urgency I16.1 Hypertensive emergency I16.9 Hypertensive crisis, unspecified
List of MS-DRGs	Scenarios 1-2: For the list of MS-DRGs, see the online posting for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter. Scenarios 3-4: 291 Heart Failure and Shock With MCC 292 Heart Failure and Shock with CC 293 Heart Failure and Shock without CC/MCC 304 Hypertension with MCC 305 Hypertension without MCC 682 Renal Failure with MCC 683 Renal Failure with CC 684 Renal Failure without CC/MCC
Inclusion/ exclusion criteria	Scenario 1: The applicant selected claims with a principal diagnosis of the ICD-10-CM codes listed in the table, as it believes this list represents the entire population of patients with essential (primary)

	hypertension as the reason for an inpatient admission. Any MS-DRG with a total discharge count of less than 11 was imputed with a count of 11. Cases with outlier payments were excluded. Scenario 2: The applicant used the same inclusion/exclusion criteria from Scenario 1, except that cases with outlier payments were included. Scenario 3: The applicant selected claims with a principal diagnosis of the ICD-10-CM codes listed in the table, but limited the case selection to MS-DRGs where the principal diagnosis was essential hypertension and no procedures were performed, as it believes this list represents a subset of cases that were most likely to benefit from the new procedural treatment option for essential (primary) hypertension. Cases with outlier payments were excluded. Scenario 4: The applicant used the same inclusion/exclusion criteria from Scenario 3, except that cases with outlier payments were included.
Charges removed for prior technology	The applicant stated that currently, there are no procedures or devices used to treat essential hypertension. Per the applicant, patients admitted inpatient for hypertension would still require stabilization on medications prior to undergoing renal denervation. Therefore, the applicant did not remove any direct or indirect charges for prior technologies being replaced.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the expected cost of the new technology by the national average cost-to-charge ratio of 0.303 for supplies and equipment from the FY 2024 IPPS/LTCH PPS final rule. The applicant stated that the estimated indirect procedural costs for hospital costs associated with the renal denervation procedure were approximated from sample hospital claims from participating clinical trial hospitals. The applicant added indirect charges related to the new technology by dividing the indirect procedure costs related to the new technology by the corresponding national average cost-to-charge ratio from the FY 2024 IPPS/LTCH PPS final rule.

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We agree with the applicant that the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter meets the cost criterion and are therefore proposing to approve the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter for new technology add-on payments for FY 2025.

An estimate for the cost of the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter is not available for publication at the time of this proposed rule. We expect the applicant to release cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. The applicant stated that there would be two components for the cost of the technology, including operating costs for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter and capital costs for the Symplicity G3™ Generator. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (*86 FR 45145*). Based on the information from the applicant, it appears that the Symplicity G3™ Generator is a capital cost. Therefore, it appears that this component is not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (*72 FR 47307* through *47308*). Any new technology add-on payment for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case.

We invite public comments on whether the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter meets the cost criterion and our proposal to approve new technology add-on payments for the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter for FY 2025 for reducing blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure, which corresponds to the Breakthrough Device designation

k. Transdermal Glomerular Filtration Rate (GFR) Measurement System Utilizing Lumitrace

MediBeacon, Inc. submitted an application for new technology add-on payments for the Transdermal GFR Measurement System utilizing Lumitrace for FY 2025. According to the applicant, the Transdermal GFR Measurement System utilizing Lumitrace is a three-component system: (1) an optical skin sensor, (2) a monitor, and (3) Lumitrace (relmapirazin), which is a proprietary fluorescent tracer agent

that glows in the presence of light and is removed from the blood exclusively by the GFR mechanism of the kidney. The technology is intended to measure GFR in patients with impaired or normal renal function during clinical conditions where the real time measurement of GFR (versus estimated measures) is clinically useful in the understanding of kidney function. We note that MediBeacon, Inc. submitted an application for new technology add-on payments for the Transdermal GFR Measurement System utilizing Lumitrace for FY 2024, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26954 through 26955), that it withdrew prior to the issuance of the FY 2024 IPPS/LTCH PPS final rule (88 FR 58919).

Please refer to the online application posting for the Transdermal GFR Measurement System utilizing Lumitrace, available at *https://mearis.cms.gov/public/publications/ntap/NTP23101671HAA,* for additional detail describing the technology.

According to the applicant, the Transdermal GFR Measurement System utilizing Lumitrace received Breakthrough Device designation from FDA on October 16, 2018, for measuring GFR in patients with impaired or normal renal function. According to the applicant, its marketing authorization request for the Transdermal GFR Measurement System utilizing Lumitrace has been filed by FDA, and it anticipates a premarket approval decision from FDA for the same indication consistent with the Breakthrough Device designation before May 1, 2024. According to the applicant, the Transdermal GFR Measurement System will not be immediately available for sale because it is waiting for premarket approval from FDA before producing large volumes of the agent, sensor, and monitor, and anticipates a limited launch prior to widespread availability.

The applicant stated that effective October 1, 2019, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of the Transdermal GFR Measurement System utilizing Lumitrace: XT25XE5 (Monitoring of kidney using fluorescent pyrazine, external approach, new technology group 5).

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the Transdermal GFR Measurement System utilizing Lumitrace, the applicant searched the FY 2022 MedPAR file for claims that had one of the ICD–10–CM codes or the ICD–10–PCS codes representing patients who are likely to require and/or benefit from real-time kidney function monitoring during the inpatient hospital stay. Using the inclusion/exclusion criteria described in the following table, the applicant identified 470,171 claims mapping to 697 MS–DRGs, including MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC) representing 15% of the identified cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $231,117, which exceeded the average case-weighted threshold amount of $134,438.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion.

[129] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

Transdermal GFR Measurement System utilizing Lumitrace COST ANALYSIS[129]	
Data Source and Time Period	FY 2022 MedPAR file
List ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for the Transdermal GFR Measurement System utilizing Lumitrace.
List of ICD-10-PCS codes	For the list of ICD-10-PCS codes, see the online posting for the Transdermal GFR Measurement System utilizing Lumitrace.
List of MS-DRGs	For the list of MS-DRGs, see the online posting for the Transdermal GFR Measurement System utilizing Lumitrace.
Inclusion/exclusion criteria	The applicant identified cases with at least one ICD-10 PCS procedure code or at least one ICD-10 CM diagnosis code (in the primary or secondary position) from the list of ICD-10-CM/PCS codes provided in the online posting, and had inpatient hospital stays with 3 or more days in the intensive care unit, as it believes this would identify a patient likely to require and/or benefit from real-time kidney function monitoring during the inpatient hospital stay. The applicant excluded managed care cases, claims submitted only for graduate medical education payments, claims with ancillary costs of zero, and claims that were statistical outliers within the MS-DRG. The applicant calculated the average charge per case for each MS-DRG, using only covered departmental charges used by CMS for rate setting. Charges for organ acquisition were not included.
Charges removed for prior technology	According to the applicant, the Transdermal GFR Measurement System utilizing Lumitrace is not expected to replace prior technologies. Therefore, the applicant did not remove any direct or indirect charges for prior technologies being replaced.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2024 IPPS/LTCH PPS final rule and the GAF from the impact file posted with the FY 2022 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion and are therefore proposing to approve the Transdermal GFR Measurement System utilizing Lumitrace for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

The applicant has not provided an estimate for the cost of the Transdermal GFR Measurement System utilizing Lumitrace at the time of this proposed rule. The applicant stated that there would be three components for the cost of the technology: the operating cost of the Transdermal GFR Measurement System Sensor, the operating cost of Lumitrace (relmapirazin) that glows in the presence of light and is removed from the blood exclusively by the GFR mechanism of the kidney, and the capital cost of the Transdermal GFR Measurement System Monitor that displays fluorescence collected by the Transdermal GFR Measurement System Sensor to provide an indication of changes in transdermal GFR over time. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant stated that the cost of the Transdermal GFR Measurement System Monitor is a capital cost. Therefore, it appears that this component is not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the Transdermal GFR Measurement System utilizing Lumitrace would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case.

We invite public comments on whether the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion and our proposal to approve new technology add-on payments for the Transdermal GFR Measurement System utilizing Lumitrace for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

l. TriClip™ G4

Abbott submitted an application for new technology add-on payments for TriClip™ G4 for FY 2025. According to the applicant, TriClip™ G4 is intended for reconstruction of the insufficient tricuspid valve through tissue approximation via a transcatheter approach. The TriClip™ G4 System consists of the TriClip™ G4 Implant,

Clip Delivery System and Steerable Guide. The applicant explained that the TriClip™ G4 Implant is a percutaneously delivered mechanical implant that helps close the tricuspid valve leaflets resulting in fixed tricuspid leaflet approximation throughout the cardiac cycle. According to the applicant, TriClip™ G4 is intended for the treatment of patients with symptomatic, severe tricuspid valve regurgitation, whose symptoms and tricuspid regurgitation (TR) severity persist despite being treated optimally with medical therapy.

Please refer to the online application posting for TriClip™ G4, available at *https://mearis.cms.gov/public/publications/ntap/NTP231016N52MH,* for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the TriClip™ G4 System received Breakthrough Device designation from FDA on November 19, 2020, for the treatment of patients with symptomatic, severe tricuspid valve regurgitation, whose symptoms and TR severity persist despite being treated optimally with medical therapy. According to the applicant, its marketing authorization request has been filed by FDA, and it anticipates a premarket approval (PMA) decision from FDA for the same indication consistent with the Breakthrough Device designation before May 1, 2024. According to the applicant, the technology is expected to be commercially available immediately after FDA approval.

According to the applicant, the following ICD–10–PCS code may be used to describe procedures involving the use of TriClip™ G4: 02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach). The applicant noted that there are no FDA-approved technologies using this procedure code. The applicant stated that ICD–10–CM diagnosis codes I07.1 (Rheumatic tricuspid insufficiency) and I36.1 (Nonrheumatic tricuspid (valve) insufficiency) may be used to currently identify the indication for TriClip™ G4 under the ICD–10–CM coding system.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for TriClip™ G4, the applicant searched the 2022 Medicare Inpatient Hospital Standard Analytical File (100%) for claims that had one of the following ICD–10–CM codes, I07.1 (Rheumatic tricuspid insufficiency) or I36.1 (Nonrheumatic tricuspid (valve) insufficiency) in the primary position, in combination with ICD–10–PCS code 02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach). Using the inclusion/exclusion criteria described in the following table, the applicant identified 235 claims mapping to two MS–DRGs, MS–DRG 266 (Endovascular Cardiac Valve Replacement and Supplement Procedures, with MCC), and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures, without MCC). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $313,389 which exceeded the average case-weighted threshold amount of $192,861.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that TriClip™ G4 meets the cost criterion.

TRICLIP™ G4 COST ANALYSIS	
Data Source and Time Period	2022 Medicare Inpatient Hospital Standard Analytical File (100%)
List of ICD-10-CM codes	I07.1 (Rheumatic tricuspid insufficiency) I36.1 (Nonrheumatic tricuspid (valve) insufficiency)
List of ICD-10-PCS codes	02UJ3JZ (Supplement tricuspid valve with synthetic substitute, percutaneous approach)
List of MS-DRGs	MS-DRG 266 Endovascular Cardiac Valve Replacement and Supplement Procedures, with MCC MS-DRG 267 Endovascular Cardiac Valve Replacement and Supplement Procedures, without MCC
Inclusion/exclusion criteria	The applicant identified cases reporting a primary diagnosis of one of the ICD-10-CM codes in this table, in combination with the ICD-10-PCS code in this table. The applicant excluded cases in MS-DRGs 216 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 219 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), and 500 (Soft Tissue Procedures with MCC) because those cases included more extensive or unrelated intervention than is typically involved for TriClip™ G4 procedures. Per the applicant, these cases comprised 1.07% of the total cases in 2022. The applicant also excluded cases with denied payment.
Charges removed for prior technology	The applicant estimated replaced technology device charges using the afore-mentioned criteria and the following criteria: 1) claims with primary ICD-10-CM diagnosis code of I07.1 or I36.1, which were by far the most common codes and would help to estimate the charges in revenue center 0278 (Other Implants); 2) claims with ICD-10 procedure code 02UJ3JZ in the first position and no additional surgery codes (codes beginning with 0), which would help to ensure the correct device was charged in revenue center 0278; 3) claims listing charges under revenue center 0278; and 4) claims indicating the number of revenue units was one. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2022 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 11.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.269 for implantable devices from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that TriClip™ G4 meets the cost criterion and are therefore proposing to approve TriClip™ G4 for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of TriClip™ G4 to the hospital to be $40,000 per procedure. According to the applicant, the TriClip™ System is composed of multiple components: the TriClip™ G4 Implant, Clip Delivery System, and Steerable Guide Catheter. The applicant stated that all the components typically required for a single procedure are sold together for a single operating cost (for example, it is the same cost per procedure whether the patient requires one or two implants). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of TriClip™ G4 would be $26,000 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether TriClip™ G4 meets the cost criterion and our proposal to approve new technology add-on payments for TriClip™ G4 for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by May 1, 2024.

m. VADER® Pedicle System

Icotec Medical, Inc. submitted an application for new technology add-on payments for the VADER® Pedicle System for FY 2025. According to the applicant, the VADER® Pedicle System is a pedicle screw system for standard posterior fixation of the spinal column used to provide stabilization of infected spinal segments after debridement of infectious tissues. According to the applicant, the VADER® Pedicle System is made from high strength carbon fiber reinforced polyether ether ketone, which provides low artifact imaging to allow for post-operative surveillance of the healing of the infected spinal segment.

Please refer to the online application posting for the VADER® Pedicle System, available at *https://mearis.cms.gov/public/publications/ntap/NTP231016CMGH3,* for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the VADER® Pedicle System received Breakthrough Device designation from FDA on July 31, 2023 for stabilizing the thoracic and/or lumbar spinal column as an adjunct to fusion in patients diagnosed with an active spinal infection (for example, spondylodiscitis, osteomyelitis) who are at risk of spinal instability, progressive spinal deformity, or neurologic compromise, following surgical debridement. The applicant stated that the technology received 510(k) clearance from FDA on February 26, 2024, for the following indication, which is the subject of the new technology add-on payment application, and is consistent with the Breakthrough Device designation: to stabilize the thoracic and/or lumbar spinal column in patients who are or will be receiving concurrent medical treatment for an active spinal infection (for example, spondylodiscitis, osteomyelitis) that, without stabilization, could lead to deterioration of bony structures and misalignment with neurological compromise. We note that the VADER® Pedicle System has received FDA 510(k) clearance for multiple indications since 2019.[130] We also note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the VADER® Pedicle System to stabilize the thoracic and/or lumbar spine as an adjunct to fusion in patients with spinal infection, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2025. According to the applicant, the technology was commercially available immediately after 510(k) clearance from FDA.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the VADER® Pedicle System. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the VADER® Pedicle System beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the VADER® Pedicle System under the ICD–10–CM coding system, describing spinal infections including osteomyelitis, discitis, and spondylopathies of various vertebral spine body parts including the cervical, thoracic, and lumbar regions. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. As previously noted, only use of the technology for the indications corresponding to the Breakthrough Device designation would be relevant for new technology add-on payment purposes. We believe the relevant ICD–10–CM codes to identify the Breakthrough Device-designated indication would be the codes included in category M46 (Other inflammatory spondylopathies) under the ICD–10–CM classification in subcategories: M46.2- (Osteomyelitis of vertebra), M46.3- (Infection of intervertebral disc (pyogenic)), M46.4- (Discitis, unspecified), M46.5- (Other infective spondylopathies), M46.8- (Other specified inflammatory spondylopathies), and M46.9- (Unspecified inflammatory spondylopathy). We are inviting public comment on the use of these ICD–10–CM diagnosis codes to identify the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the VADER® Pedicle System, the applicant searched the FY 2022 MedPAR file for claims reporting a combination of ICD–10–CM/PCS codes as listed in the online posting for the VADER® Pedicle System. The applicant believes these cases represent patients who have undergone fusion procedures and have been diagnosed with an active spinal infection (such as spondylodiscitis or osteomyelitis), and these patients are at risk of spinal instability, progressive spinal deformity, or neurologic compromise following surgical debridement, making them suitable candidates for the use of the technology. Using the inclusion/exclusion criteria described in the following table, the applicant identified 2,116 claims mapping to 22 MS–DRGs, with none exceeding more than 15% of the total identified cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $473,636, which exceeded the average case-weighted threshold amount of

[130] K222789, January 9, 2023; K200596, October 13, 2020; K193423, May 22, 2020; and K190545, June 20, 2019.

$197,922. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the VADER® Pedicle System meets the cost criterion.

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VADER® Pedicle System COST ANALYSIS[131]	
Data Source and Time Period	FY 2022 MedPAR proposed rule file
List ICD-10-PCS codes	For the list of ICD-10-PCS codes, see the online posting for the VADER® Pedicle System.
List of ICD-10-CM codes	For the list of ICD-10-CM codes, see the online posting for the VADER® Pedicle System.
List of MS-DRGs	For the list of MS-DRGs, see the online posting for the VADER® Pedicle System.
Inclusion/exclusion criteria	The applicant identified cases that had an ICD-10-CM code and an ICD-10-PCS code from the tables of codes listed in the online posting for the VADER® Pedicle System, as it believes these cases represent patients who have undergone fusion procedures and have been diagnosed with an active spinal infection (such as spondylodiscitis or osteomyelitis), and these patients are at risk of spinal instability, progressive spinal deformity, or neurologic compromise following surgical debridement, making them suitable candidates for the use of this technology. The applicant only included MS-DRGs with case frequencies greater than 11. Per the applicant, it also included MS-DRGs 458 and 854 with fewer than 11 cases in the analysis, because the applicant considered these MS-DRGs highly relevant to the technology. The MS-DRGs with a total discharge count of less than 11 were imputed with a count of 11. Only approved charges were used in the calculation of charges. Hospitals were removed from the calculation of charges if they were identified within the MedPAR data but not present within the FY 2024 Standardizing File provided by CMS.
Charges removed for prior technology	According to the applicant, the VADER® Pedicle System would replace the screws, set screws, and rods used in the spinal procedure. The applicant stated that it determined the unit prices for competitor screws, rods, and set screws using an analysis of literature and competitor cost sources. The applicant computed the total cost for an average procedure involving five screws, five set screws, and two rods. The applicant then converted the cost for an average procedure to a charge using the national cost-to-charge ratio of 0.269 for the implantable devices from the FY 2024 IPPS/LTCH PPS final rule to calculate an average charge amount. The applicant did not remove any indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the FY 2022 MedPAR preliminary rule file (fee for service claims only) and standardizing and impact files posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant determined the cost per patient based on the average number of spinal segments from the VADER® Pedicle System. The applicant stated that an average of five pedicle screws, five set screws, and two rods would be used for a spinal fusion procedure. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.269 for Implantable Devices from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

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We agree with the applicant that the VADER® Pedicle System meets the cost criterion and are therefore proposing to approve the VADER® Pedicle System for new technology add-on payments for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the VADER® Pedicle System to the hospital to be $43,450 per patient. According to the applicant, the unit prices are $6,500 for a pedicle screw, $4,600 for a rod, and $350 for a set screw. The applicant stated that an average of five pedicle screws, two rods, and five set screws would be used for a spinal fusion procedure. The applicant calculated the total cost of the technology by multiplying the unit price of each component by the average number of that component used in the procedure. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65% of the average cost of the technology, or 65% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the VADER® Pedicle System would be $28,242.50 for FY 2025 (that is, 65% of the average cost of the technology).

We invite public comments on whether the VADER® Pedicle System meets the cost criterion and our proposal to approve new technology add-on payments for the VADER® Pedicle System for FY 2025, when used

[131] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

to stabilize the thoracic and/or lumbar spinal column in patients who are or will be receiving concurrent medical treatment for an active spinal infection (for example, spondylodiscitis, osteomyelitis) that, without stabilization, could lead to deterioration of bony structures and misalignment with neurological compromise.

n. ZEVTERA™ (Ceftobiprole Medocaril)

Basilea Pharmaceutica International Ltd, Allschwil submitted an application for new technology add-on payments for ZEVTERA™ (ceftobiprole medocaril) for FY 2025. According to the applicant, ZEVTERA™ is an advanced intravenous cephalosporin antibiotic designed to combat infections caused by antibiotic resistant pathogens. The applicant stated that ZEVTERA™ targets a wide range of Gram-positive and Gram-negative bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA), *Streptococcus pneumoniae,* including penicillin-non-susceptible pneumococci (PNSP) and *Enterococcus faecalis,* as well as non-Extended Spectrum Beta-Lactamase (non-ESBL) producing Enterobacterales. The applicant noted that ZEVTERA™'s bactericidal activity is achieved by binding to essential penicillin-binding proteins, disrupting the synthesis of the bacterial cell wall's peptidoglycan layer and leading to bacterial cell death, which differentiates it from other beta-lactams by effectively addressing MRSA. Per the applicant, ZEVTERA™ is stable against certain beta-lactamases in both gram-positive and gram-negative bacteria. The applicant stated that Phase 3 studies submitted to the FDA demonstrate its non-inferiority compared to standard treatments in various infections, including Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections (ABSSSI), and community-acquired bacterial pneumonia (CABP).

Please refer to the online application posting for ZEVTERA™, available at *https://mearis.cms.gov/public/publications/ntap/NTP2310161DBB8,* for additional detail describing the technology and the disease treated by the technology.

According to the applicant, ZEVTERA™ received QIDP designations for CABP on July 20, 2015, for ABSSI on August 7, 2015, and for SAB on December 8, 2017. According to the applicant, its marketing authorization request for ZEVTERA™ has been filed by FDA, and it anticipates an NDA decision from FDA for the same indications consistent with the QIDP designations by July 1, 2024. According to the applicant, ZEVTERA™ will be commercially available immediately after FDA approval. We note that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), ZEVTERA™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2024, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2025), as provided in § 412.87(f)(3). According to the applicant, for CABP and ABSSSI, ZEVTERA™ is dosed at 500mg and administered three times daily (Q8h) as a 2-hour intravenous infusion for 5–14 days. For SAB, it is administered four times daily (Q6h) for the first 8 days, followed by Q8h daily infusion for the subsequent days, up to a total of 42 days.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify ZEVTERA™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for ZEVTERA™ beginning in FY 2025. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for ZEVTERA™ under the ICD–10–CM coding system, describing SAB, ABSSSI, and CABP. Please refer to the online application posting for the complete list of ICD–10–CM (and PCS) codes provided by the applicant. We believe the relevant combination of ICD–10–CM codes to identify the indication of SAB would be: R78.81 (Bacteremia) in combination with B95.61 (Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere) or B95.62 (Methicillin resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of SAB for purposes of the new technology add-on payment, if approved.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2022 MedPAR file using different sets of ICD–10–CM codes in the first five diagnosis positions to identify potential cases representing different cohorts of patients who may be eligible for ZEVTERA™. The applicant performed the same analysis on ABSSSI, CABP, and SAB cases individually and for all indications combined.

For the first analysis, the applicant searched for claims with a diagnosis code for ABSSSI using the ICD–10–CM codes listed in the online posting for ZEVTERA™. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 261,397 claims mapping to 663 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $114,279, which exceeded the average case-weighted threshold amount of $63,767.

For the second analysis, the applicant searched for claims with a diagnosis code for CABP using the ICD–10–CM codes listed in the online posting for ZEVTERA™. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 635,628 claims mapping to 611 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $143,456, which exceeded the average case-weighted threshold amount of $78,778.

For the third analysis, the applicant searched for claims with a diagnosis code for SAB using the ICD–10–CM codes listed in the online posting for ZEVTERA™. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 105,068 claims mapping to 626 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $165,809, which exceeded the average case-weighted threshold amount of $82,238.

For the fourth analysis, the applicant searched for claims with diagnosis codes for ABSSSI, CABP, or SAB in the first five positions on a claim, using the ICD–10–CM codes listed in the online posting for ZEVTERA™. The applicant used the inclusion/exclusion criteria described in the table that follows later in this section. Under this analysis, the applicant identified 958,104 claims mapping to 680 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $137,861, which exceeded the average case-weighted threshold amount of $75,097.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that ZEVTERA™ meets the cost criterion.

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ZEVTERA™ COST ANALYSIS[132]	
Data Source and Time Period	FY 2022 MedPAR file
List of ICD-10-CM codes	For the lists of ICD-10-CM codes, see the online posting for ZEVTERA™
List of MS-DRGs	For the lists of MS-DRGs, see the online posting for ZEVTERA™
Inclusion/ exclusion criteria	Analysis 1: The applicant selected claims based on the ICD-10-CM codes provided in the online posting, as it believes this list represents cases of ABSSSI diagnosis. Analysis 2: The applicant selected claims based on the ICD-10-CM codes provided in the online posting, as it believes this list represents cases of CABP diagnosis. Analysis 3: The applicant selected claims based on the ICD-10-CM codes provided in the online posting, as it believes this list represents cases of SAB diagnosis. Analysis 4: The applicant selected claims based on the ICD-10-CM codes provided in the online posting, as it believes this list represents diagnosis codes for ABSSSI, CABP, and SAB. For each analysis, the applicant included 100% of the cases identified which is inclusive of the imputed claims that occurred when an MS-DRG had fewer than 11 claims. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant did not remove any of charges as it believes ZEVTERA™ will be used in addition to other therapies. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2024 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 18.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2024 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2024 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

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We agree with the applicant that ZEVTERA™ meets the cost criterion and are therefore proposing to approve ZEVTERA™ for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization for the indication corresponding to the QIDP designation by July 1, 2024. As an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), ZEVTERA™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2024, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2025), as provided in § 412.87(f)(3). If ZEVTERA™ receives FDA marketing authorization before July 1, 2025, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2025, no new technology add-on payments would be made for cases involving the use of ZEVTERA™ for FY 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the pricing for this treatment is set at $125 per vial, and the recommended dosage varies depending on the condition being treated. The applicant stated that for ABSSSI and CABP, the suggested daily dose is 3 vials per day for a duration of 5–14 days, resulting in an estimated average cost of $3,750 for a 10-day therapy. The applicant noted that for SAB, the recommended dose is every 6 hours for the first 8 days, followed by every 8 hours for up to 42 days. The applicant made the assumption that patients would be inpatient for 28 days and then continue the therapy as an outpatient for up to 42 days, which resulted in an average inpatient cost of $11,500. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for technologies designated as QIDPs to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of ZEVTERA™ for FY 2025 would be $8,625.00 for the indication of SAB and $2,812.50 for the indications of ABSSSI and CABP (that is, 75% of the average cost of the technology).

We invite public comments on whether ZEVTERA™ meets the cost criterion and our proposal to approve new technology add-on payments for ZEVTERA™ for FY 2025 for SAB, ABSSSI, and CABP, subject to the technology receiving FDA marketing

[132] Lists referenced here may be found in the cost criterion codes and MS–DRGs attachment included in the online posting for the technology.

authorization consistent with its QIDP designations by July 1, 2024.

7. Proposed Change to the Method for Determining Whether a Technology Would Be Within Its 2- to 3-Year Newness Period When Considering Eligibility for New Technology Add-On Payments

As discussed previously in this rule, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. The regulations at 42 CFR 412.87 implement these provisions. As further discussed in FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use the FDA marketing authorization date as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRG weights. In specific circumstances, we have recognized a date later than the FDA marketing authorization date as the appropriate starting point for the 2- to 3-year newness period. For example, we have recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval or clearance. The costs of the new medical service or technology, once paid for by Medicare for this 2- to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we stated it is appropriate to limit the add-on payment window for technologies that have passed this 2- to 3-year timeframe.

As discussed previously in this rule, our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the three-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year, that is, after April 1 (70 FR 47362).

We have not implemented a policy to stop new technology add-on payment in the middle of the fiscal year (for example, during the month that a technology reaches its three-year anniversary date of entry onto the U.S. market) because, as we discussed in the FY 2005 IPPS final rule, we believe that predictability is an important aspect of the prospective payment system methodology. Accordingly, we believe that it is appropriate to apply a consistent payment methodology for new technologies throughout the fiscal year (69 FR 49016).

As previously discussed, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA marketing authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. We also finalized that, beginning with FY 2025 applications, in order to be eligible for consideration for new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA approval or clearance by May 1 (rather than July 1) of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products).

As we summarized in the FY 2024 IPPS/LTCH PPS final rule, commenters raised concerns that this policy would adversely impact their ability to receive maximum flexibility with respect to when to apply to FDA and when they apply for new technology add-on payment (88 FR 58953). Many commenters expressed specific concerns regarding moving the FDA marketing authorization deadline to May 1 and the impact it would have on how long technologies may be eligible for new technology add-on payment. Several of the commenters asserted that this policy change would prevent a 3-year new technology add-on payment duration for almost all applicants, as only those technologies that receive FDA marketing authorization in April would be eligible for 3 years of new technology add-on payments, shortening the window from 3 months under the former policy (April 1 until July 1) to just 1 month (April 1 until May 1) (88 FR 58954). In response, we noted in that even under the former policy, not all applicants receive the full 3 years of new technology add on payments, and that there are many factors (including timing of interactions with the FDA and manufacturing readiness) that can delay a technology's approval by the FDA that would disrupt a technology's ability to receive the full 3 years of payment. However, we also noted the commenters' concerns regarding the shortened time period between April 1 and May 1 under the new policy and stated that we would consider for future rulemaking how we assess new technology add-on payment eligibility in the third year of newness, such as consideration of adjusting the April 1 cutoff to allow for a longer window of eligibility (88 FR 58955).

After further consideration of commenters' concerns that the policy we finalized in the FY 2024 IPPS/LTCH PPS final rule may limit the ability of new technology add-on payment applicants to be eligible for a third year of new technology add-on payments due to the shortened timeframe between April 1 and May 1, we agree that there may be merit to modifying our current 6-month guideline to provide additional flexibility for applications submitted in accordance with this new policy. While technologies that are FDA approved or cleared in April, and technologies with a documented delay in availability on the U.S. market such that the product's entry onto the U.S. market falls within the second half of the fiscal year, would still be eligible for a third year of new technology add-on payments under current policy, we agree that the change in the FDA marketing authorization deadline from July 1 to May 1 may limit the ability of new technology add-on payment applicants to be eligible for 3 years of new technology add-on payments. Therefore, we are proposing to change the April 1 cutoff for determining whether a technology would be within its 2- to 3-year newness period when considering eligibility for

new technology add-on payments. We believe this proposed change would continue the flexibility applicants had with respect to when they apply to FDA and when they apply for new technology add-on payment, while preserving a predictable and consistent payment methodology for new technologies throughout the fiscal year.

Specifically, we are proposing that beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we would extend new technology add-on payments for an additional fiscal year when the three-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. We are proposing that this policy change would become effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year to allow additional flexibility for those applications for new technologies which were first subject to the change in the deadline for FDA marketing authorization from July 1 to May 1. Therefore, for technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we would continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered ''new'' for purposes of new technology add-on payments. Similarly, we are also proposing that beginning with applications for new technology add-on payments for FY 2026, we would use the start of the fiscal year (October 1) instead of April 1 to determine whether to approve new technology add-on payment for that fiscal year.

We are seeking public comment on our proposal to change the April 1 cutoff to October 1 for determining whether a technology would be within its 2- to 3-year newness period when considering eligibility for new technology add-on payments, beginning in FY 2026, effective for those technologies that are approved for new technology add-on payments starting in FY 2025 or a subsequent year.

8. Proposed Change to the Requirements Defining an Active FDA Marketing Application for the Purpose of New Technology Add-On Payment Application Eligibility

As previously discussed, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission, and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958).

As we discussed further in the FY 2024 IPPS/LTCH PPS final rule, the documentation of FDA acceptance or filing of a marketing authorization request must be provided at the time of new technology add-on payment application, and be consistent with the type of FDA marketing authorization the applicant has submitted to FDA. We stated that we only accept new technology add-on payment applications once FDA has received all of the information necessary to determine whether it will accept (such as in the case of a 510(k) premarket submission or De Novo Classification request) or file (such as in the case of a PMA, NDA, or BLA) the application as demonstrated by documentation of the acceptance/filing that is provided by FDA. The applicant is required to submit documentation with its new technology add-on payment application to demonstrate that FDA has determined that the application is sufficiently complete to allow for substantive review by the FDA (88 FR 58955).

We also explained that, for the purposes of new technology add-on payment applications, we consider an FDA marketing authorization application to be in an active status when it has not been withdrawn, is not the subject of a Complete Response Letter or final decision from FDA to refuse to approve the application, and is not on hold (88 FR 58955 through 58956).

As noted in the FY 2024 final rule, we collaborated with FDA in developing the terminology used for purposes of this policy, and the intent behind using the terms we did was to ensure that the requirement could apply to and be inclusive of the various FDA applications and approval pathways for different types of drugs and devices. As such, we did not use terms defined in statute or existing regulations or terms defined by FDA (88 FR 58955). While FDA may consider an application for an FDA marketing authorization to be under active review despite a hold status, under our current policy we do not consider marketing authorization applications in a hold status with FDA to be in an active status for the purposes of new technology add-on payment application eligibility. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58956) our intent with respect to considering applications that are on hold at the time of new-technology add-on payment application submission to be inactive was to ensure that applicants are far enough along in the FDA review process that applicants would be able to reasonably provide sufficient information at the time of new technology add on payment application for CMS to identify critical questions regarding the technology's eligibility for add-on payments and to allow the public to assess the relevant new technology evaluation criteria in the proposed rule. As noted in the FY 2024 final rule (88 FR 58956), we have received applications over the years for technologies that are in a hold status with up to 360 days allowed for submission of additional information.

We also recognize that applications for FDA marketing authorization may go in and out of a hold status at various stages during the FDA application process and for various reasons. The maximum length of a hold status can vary based on the FDA approval pathway, such that the time remaining for an applicant to resolve the hold may vary from days to several months after the start of the new technology add-on payment application cycle, depending on the FDA pathway, reason(s) for the hold status, and how the timing of the hold coincides with the annual new technology add-on payment application submission date. Additionally, FDA may need to issue secondary letters of request for additional information, often depending on the quality of initial response from the applicant. Accordingly, while we continue to believe that an application that is in a hold status with FDA pending additional information may lack critical information that is needed to evaluate whether the technology meets the eligibility criteria, we also recognize the

variability in the reasons for a hold status and the varying lengths of time for which an application can be on hold with FDA, such that some applicants may be farther along in the process to obtain FDA marketing authorization at the time of the hold.

After further consideration, based on the variability in the timing of and reasons underlying hold statuses with FDA, we believe it is appropriate to propose to update our policy. Specifically, we are proposing, beginning with new technology add-on payment applications for FY 2026, to no longer consider a hold status to be an inactive status for the purposes of eligibility for the new technology add-on payment. We would continue to consider an application to be in an inactive status where it is withdrawn, the subject of a Complete Response Letter, or the subject of a final decision from FDA to refuse to approve the application. Because of the variety of circumstances for which a technology may be in a hold status, as previously discussed, we note that we may reassess this policy for future years, if finalized, based on ongoing experience.

We invite public comments on our proposal to no longer consider a hold status to be an inactive status for the purposes of eligibility for new technology add-on payment, beginning with new technology add-on payment applications for FY 2026.

9. Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment for Gene Therapies Indicated for Sickle Cell Disease

As discussed previously in this section, section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for a new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. Under our current policy, as set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for a medical product designated by the FDA as a Qualified Infectious Disease Product [QIDP] or approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs [LPAD]) of the estimated costs of the new technology or medical service.

Since establishing the new technology add-on payment, we have been cautious about increasing the new technology add-on payment percentage. As stated in the May 4, 2001 proposed rule (66 FR 22695), we believe limiting the new technology add-on payment percentage would provide hospitals an incentive for continued cost-effective behavior in relation to the overall costs of the case. In the FY 2020 IPPS/LTCH PPS final rule, in adopting the general increase in the new technology add-on payment percentage from 50 percent to 65 percent, we stated that we believed that 65 percent would be an incremental increase that would reasonably balance the need to maintain the incentives inherent to the prospective payment system while also encouraging the development and use of new technologies. We continue to believe that it is important to balance these incentives in assessing any potential change to the new technology add-on payment calculation.

In the FY 2020 IPPS/LTCH PPS final rule, we also finalized an increase in the new technology add-on payment percentage for QIDPs from 65 percent to 75 percent. We stated that we shared commenters' concerns related to antimicrobial resistance and its serious impact on Medicare beneficiaries and public health overall. We noted that the Centers for Disease Control and Prevention (CDC) described antimicrobial resistance as ''one of the biggest public health challenges of our time.'' We stated that we believe that Medicare beneficiaries may be disproportionately impacted by antimicrobial resistance due in large part to the unique vulnerability to drug-resistant infections (for example, due to age-related and/or disease-related immunosuppression, greater pathogen exposure from via catheter use) among individuals aged 65 or older. We further stated that antimicrobial resistance results in a substantial number of additional hospital days for Medicare beneficiaries, resulting in significant unnecessary health care expenditures.

To address the continued issues related to antimicrobial resistance resulting in a substantial number of increased hospital days and significant unnecessary health care expenditures for Medicare beneficiaries, in the FY 2021 IPPS/LTCH PPS final rule, we finalized a proposal to expand the alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway and to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway, from 65 percent to 75 percent, consistent with the new technology add-on payment percentage for a product that is designated by FDA as a QIDP, beginning with discharges occurring on or after October 1, 2020 (85 FR 58739).

Since finalizing our current policy for QIDPs and LPADs, we continue to receive feedback from interested parties regarding the adequacy of new technology add-on payments for certain categories of technologies, including cell and gene therapies to treat sickle cell disease (SCD). Although we still believe it is prudent to proceed cautiously with increasing the new technology add-on payment percentage, we recognize that SCD, the most common inherited blood disorder, has historically had limited treatment options. In addition, hospitalizations and other health episodes related to SCD cost the health system $3 billion per year.[133] We further note that the administration has identified a need to address SCD and has made a commitment to improving outcomes for patients with SCD by facilitating access to cell and gene therapies that treat SCD.[134]

Accordingly, we believe that further facilitating access to these gene therapies for Medicare beneficiaries with SCD may have the potential to simultaneously improve the health of impacted Medicare beneficiaries and potentially lead to long-term savings in the Medicare program. We also note that some gene therapies that treat SCD are among the costliest treatments to date, and we are concerned about a hospital's ability to sustain a potential financial loss to provide access to such treatments. As we discussed when we increased the new technology add-on payment for QIDPs in the FY 2020 IPPS/LTCH PPS final rule and products approved under FDA's LPAD in the FY 2021 IPPS/LTCH PPS final rule from 65 percent to 75 percent, we believe that it may be appropriate to increase the maximum add-on amount in limited cases where the current new technology add-on payment does not provide a sufficient incentive for the use of a new technology, which we believe may be the case for gene therapies that treat SCD. Accordingly, and consistent with our new technology add-on payment policy for products designated by the FDA as a QIDP or LPAD, we believe

[133] Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments *https://www.hhs.gov/about/news/2024/01/30/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.html.*

[134] Biden-Harris Administration Announces Action to Increase Access to Sickle Cell Disease Treatments *https://www.hhs.gov/about/news/2024/01/30/biden-harris-administration-announces-action-increase-access-sickle-cell-disease-treatments.html.*

there would be merit in also increasing the new technology add-on payment percentage for gene therapies that are indicated and used for the treatment of SCD to 75 percent.

Therefore, we are proposing that, subject to our review of the new technology add-on payment eligibility criteria, for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule for the treatment of SCD, effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We note that, if finalized, these payment amounts would only apply to any gene therapy indicated and used specifically for the treatment of SCD that CMS determines in the FY 2025 IPPS/LTCH PPS final rule meets the criteria for approval for new technology add-on payment. We are also proposing to add new § 412.88(a)(2)(ii)(C) and § 412.88(b)(2)(iv) to reflect this proposed change to the calculation of the new technology add-on payment amount, beginning in FY 2025 and concluding at the end of the 2- to 3-year newness period for each such therapy. With this incremental increase, we believe hospitals would continue to have an incentive to balance the desirability of using the new technology for patients as medically appropriate while also maintaining an incentive for continued cost-effective behavior in relation to the overall costs of the case.

We invite public comments on this proposal to temporarily increase the new technology add-on payment percentage to 75 percent for a gene therapy that is indicated and used for the treatment of SCD as described previously. We also seek comment on whether we should make this proposed 75 percent add-on payment percentage available only to applicants that meet certain additional criteria, such as attesting to offering and/or participating in outcome-based pricing arrangements with purchasers (without regard to whether the specific purchaser availed itself of the outcome-based arrangements), or otherwise engaging in behaviors that promote access to these therapies at lower cost.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2025 hospital wage index based on the statistical areas appears under section III.B. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, IV. The OMB control number for this information collection request is 0938–0050, which expires on September 30, 2025. Section 1886(d)(3)(E) of the Act also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2025 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2025 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. (The OMB control number for approved collection of this information is 0938–0907, which expires on January 31, 2026.) A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2025 wage index appears under section III.E. of the preamble of this proposed rule.

2. Proposed Core-Based Statistical Areas (CBSAs) for the FY 2025 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005 (69 FR 49026 through 49032), we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2021) are based on revised OMB delineations issued on Sept 14, 2018, in OMB Bulletin No. 18–04.[135] OMB Bulletin No. 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census and the American Community Survey (ACS) and Census Bureau population estimates for 2015.

Historically, OMB issued major revisions to statistical areas every 10 years, based on the results of the decennial census and occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On February 28, 2013, OMB issued Bulletin No. 13–01. CMS adopted these delineations, based on the results of the 2010 census, effective beginning with the FY 2015 IPPS wage index (79 FR 49951 through 49957). OMB subsequently issued Bulletin No. 15–01 on July 15, 2015, followed by OMB Bulletin No. 17–01 on August 15, 2017, which provided updates to and superseded OMB Bulletin No. 15–01. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015 and were based on the

[135] We note that while OMB Bulletin 20–01 superseded Bulletin No. 18–04, it included no changes that required CMS to formally adopt the revisions.

application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. OMB Bulletin No. 17–01 was superseded by the April 10, 2018 OMB Bulletin No. 18–03, and then by the September 14, 2018 OMB Bulletin No. 18–04. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. In FY 2021, we adopted the updates set forth in OMB Bulletin No. 18–04 (85 FR 58743 through 58753). Thus, most recently in the FY 2024 IPPS/LTCH PPS final rule, we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, and 18–04.

In the July 16, 2021 **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the ACS. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

B. Proposed Implementation of Revised Labor Market Area Delineations

We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the IPPS wage index system by creating a more accurate representation of current geographic variations in wage levels. Therefore, we are proposing to implement the revised OMB delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, beginning with the FY 2025 IPPS wage index. We are proposing to use these revised delineations to calculate area wage indexes in a manner that is generally consistent with the CMS' implementation of CBSA-based wage index methodologies.

CMS has recognized that hospitals in certain areas may experience a negative impact on their IPPS payment due to the proposed adoption of the revised OMB delineations and has finalized transition policies to mitigate negative financial impacts and provide stability to year-to-year wage index variations. We refer readers to the FY 2015 IPPS final rule (79 FR 49956 through 49962) for discussion of the transition period finalized the last time CMS adopted revised OMB delineations after a decennial census. In the FY 2020 final rule (84 FR 42336–42337), CMS finalized a wage index transition policy to apply a 5 percent cap on any decrease that hospitals may experience in their final wage index from the prior fiscal year. In FY 2023, the 5 percent cap policy was made permanent for all acute care hospitals. This 5 percent cap on reductions policy is discussed in further detail in section III.G.6 of the preamble of this proposed rule. We believe it is important for the IPPS to use the updated labor market area delineations in order to maintain a more accurate and up-to date payment system that reflects the reality of current labor market conditions. We believe the 5 percent cap policy will sufficiently mitigate significant disruptive financial impacts on hospitals that are negatively affected by the proposed adoption of the revised OMB delineations and thus, we are not proposing a transition period for these hospitals.

1. Micropolitan Statistical Areas

The OMB ''2020 Standards'' define a ''Micropolitan Statistical Area'' as being associated with at least one urban area that has a population of at least 10,000, but less than 50,000. A Micropolitan Statistical Area comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county or counties as measured through commuting (86 FR 37778). We refer to these areas as Micropolitan Areas. Since FY 2005, we have treated Micropolitan Areas as rural and included hospitals located in Micropolitan Areas in each State's rural wage index. We refer readers to the FY 2005 IPPS final rule (69 FR 49029 through 49032) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49952) for a complete discussion regarding this policy and our rationale for treating Micropolitan Areas as rural. Based upon the new 2020 Decennial Census data, a number of urban counties have switched status and have joined or became Micropolitan Areas, and some counties that once were part of a Micropolitan Area, under current OMB delineations, have become urban. Overall, there are a similar number of Micropolitan Areas (542) under the new OMB delineations based on the 2020 Census as existed under the latest data from the 2010 Census (541). We believe that the best course of action would be to continue the policy established in the FY 2005 IPPS final rule and include hospitals located in Micropolitan Areas in each State's rural wage index. These areas continue to be defined as having relatively small urban cores (populations of 10,000–49,999). We do not believe it would be appropriate to calculate a separate wage index for areas that typically may include only a few hospitals for the reasons set forth in the FY 2005 IPPS/LTCH PPS final rule (69 FR 49029 through 49032) and the FY 2015 IPPS final rule (79 FR 49952). Therefore, in conjunction with our proposal to implement the new OMB statistical area delineations beginning in FY 2025, we are proposing to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

2. Metropolitan Divisions

According to OMB's ''2020 Standards'' (86 FR 37776), a metropolitan division is a county or group of counties within a metropolitan statistical area (MSA) with a population of at least 2.5 million. Thus, MSAs may be subdivided into metropolitan divisions. A county qualifies as a ''main county'' of a metropolitan division if 65 percent or more of workers living in the county also work within the county and the ratio of the number of workers working in the county to the number of workers living in the county is at least 0.75. A county qualifies as a ''secondary county'' if 50 percent or more, but less than 65 percent, of workers living in the county also work within the county and the ratio of the number of workers working in the county to the number of workers living in the county is at least 0.75. After all the main and secondary counties are identified and grouped, each additional county that already has qualified for inclusion in the MSA falls within the metropolitan division associated with the main/secondary county or counties with which the county at issue has the highest employment interchange measure. Counties in a metropolitan division must be contiguous. In the FY 2005

IPPS final rule (69 FR 49029), CMS finalized our policy to use the metropolitan divisions where applicable under the CBSA definitions. CMS concluded that including the metropolitan divisions in the CBSA definitions most closely approximated the labor market delineation from the ''Primary Metropolitan Statistical Areas'' delineations in place prior to FY 2005.

Under the current delineations, 11 MSAs are subdivided into a total of 31 metropolitan divisions. The revised OMB delineations have subdivided two additional existing MSAs into metropolitan divisions relative to the previous delineations. Under the proposed delineations, 13 MSAs (the 11 currently subdivided MSAs plus two additional MSAs) are subdivided into 37 metropolitan divisions. Since the configurations of most subdivided MSAs remain substantially similar in the revised delineations compared to those used in FY 2024, in order to maintain continuity and predictability in labor market delineations, we are proposing to continue our policy to include metropolitan divisions as separate CBSAs for wage index purposes.

3. Change to County-Equivalents in the State of Connecticut

In a June 6, 2022 Notice (87 FR 34235 through 34240), the Census Bureau announced that it was implementing the State of Connecticut's request to replace the 8 counties in the State with 9 new ''Planning Regions.'' Planning regions now serve as county-equivalents within the CBSA system. OMB Bulletin No. 23–01 is the first set of revised delineations that referenced the new county-equivalents for Connecticut. We have evaluated the change in hospital assignments for Connecticut hospitals and are proposing to adopt the planning regions as county equivalents for wage index purposes. As all forthcoming county-based delineation data will utilize these new county-equivalent definitions for the Connecticut, we believe it is necessary to adopt this migration from counties to planning region county-equivalents in order to maintain consistency with OMB Bulletin No. 23–01 and future OMB updates. We are providing the following crosswalk for each hospital in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

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CCN	FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
070002	09003	HARTFORD	25540	09110	CAPITOL	25540
070003	09015	WINDHAM	49340	09150	NORTHEASTERN CONNECTICUT	07
070004	09005	LITCHFIELD	07	09160	NORTHWEST HILLS	07
070005	09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
070006	09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
070007	09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
070008	09013	TOLLAND	25540	09110	CAPITOL	25540
070010	09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
070011	09005	LITCHFIELD	07	09160	NORTHWEST HILLS	07
070012	09013	TOLLAND	25540	09110	CAPITOL	25540
070015	09005	LITCHFIELD	07	09190	WESTERN CONNECTICUT	14860
070016	09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
070017	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
070018	09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
070019	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300

CCN	FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
070020	09007	MIDDLESEX	25540	09130	LOWER CONNECTICUT RIVER VALLEY	25540
070021	09015	WINDHAM	49340	09180	SOUTHEASTERN CONNECTICUT	35980
070022	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
070024	09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
070025	09003	HARTFORD	25540	09110	CAPITOL	25540
070027	09003	HARTFORD	25540	09110	CAPITOL	25540
070028	09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
070029	09003	HARTFORD	25540	09140	NAUGATUCK VALLEY	47930
070031	09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
070033	09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
070034	09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
070035	09003	HARTFORD	25540	09110	CAPITOL	25540
070036	09003	HARTFORD	25540	09110	CAPITOL	25540
070038	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
070039	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
07B010	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
07B022	09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
07B033	*09005*	*LITCHFIELD*	*07*	*09190*	*WESTERN CONNECTICUT*	*14860*

We note that we are proposing that the remote location currently indicated with 07B033 will be located in the same CBSA as the main provider 070033. Therefore, consistent with the policy for remote locations of multicampus hospitals discussed in FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), it will no longer be necessary to identify this remote location separately from the main provider for wage index purposes.

We also note, as discussed in Section III.B.3 of the preamble of this proposed rule, we propose to add both of the newly proposed rural planning areas in Connecticut to the list of ''Lugar'' counties.

4. Urban Counties That Would Become Rural Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the revised OMB statistical area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. Our analysis shows that a total of 53 counties (and county equivalents) and 33 hospitals that were once considered part of an urban CBSA would be considered to be located in a rural area, beginning in FY 2025, under these revised OMB delineations. The following chart lists the 53 urban counties that would be rural if we finalize our proposal to implement the revised OMB delineations. We note that there are four cases (CBSA 14100 [Bloomsburg-Berwick, PA], CBSA 19180 [Danville, IL], CBSA 20700 [East Stroudsburg, PA], and CBSA 35100 [New Bern, NC]) where all constituent counties in an urban CBSA would become rural under the revised OMB delineations.

COUNTIES THAT WOULD BECOME RURAL			
FIPS County Code	County Name	Current CBSA	Current CBSA Name
01129	WASHINGTON	33660	Mobile, AL
05025	CLEVELAND	38220	Pine Bluff, AR
05047	FRANKLIN	22900	Fort Smith, AR-OK
05069	JEFFERSON	38220	Pine Bluff, AR
05079	LINCOLN	38220	Pine Bluff, AR
10005	SUSSEX	41540	Salisbury, MD-DE
13171	LAMAR	12060	Atlanta-Sandy Springs-Alpharetta, GA
16077	POWER	38540	Pocatello, ID
17057	FULTON	37900	Peoria, IL
17077	JACKSON	16060	Carbondale-Marion, IL
17087	JOHNSON	16060	Carbondale-Marion, IL
17183	VERMILION	19180	Danville, IL
17199	WILLIAMSON	16060	Carbondale-Marion, IL
18121	PARKE	45460	Terre Haute, IN
18133	PUTNAM	26900	Indianapolis-Carmel-Anderson, IN
18161	UNION	17140	Cincinnati, OH-KY-IN
21091	HANCOCK	36980	Owensboro, KY
21101	HENDERSON	21780	Evansville, IN-KY
22045	IBERIA	29180	Lafayette, LA
24001	ALLEGANY	19060	Cumberland, MD-WV
24047	WORCESTER	41540	Salisbury, MD-DE
25011	FRANKLIN	44140	Springfield, MA
26155	SHIAWASSEE	29620	Lansing-East Lansing, MI
27075	LAKE	20260	Duluth, MN-WI
28031	COVINGTON	25620	Hattiesburg, MS
31051	DIXON	43580	Sioux City, IA-NE-SD
36123	YATES	40380	Rochester, NY

COUNTIES THAT WOULD BECOME RURAL			
FIPS County Code	County Name	Current CBSA	Current CBSA Name
37049	CRAVEN	35100	New Bern, NC
37077	GRANVILLE	20500	Durham-Chapel Hill, NC
37085	HARNETT	22180	Fayetteville, NC
37087	HAYWOOD	11700	Asheville, NC
37103	JONES	35100	New Bern, NC
37137	PAMLICO	35100	New Bern, NC
42037	COLUMBIA	14100	Bloomsburg-Berwick, PA
42085	MERCER	49660	Youngstown-Warren-Boardman, OH-PA
42089	MONROE	20700	East Stroudsburg, PA
42093	MONTOUR	14100	Bloomsburg-Berwick, PA
42103	PIKE	35084	Newark, NJ-PA
45027	CLARENDON	44940	Sumter, SC
48431	STERLING	41660	San Angelo, TX
49003	BOX ELDER	36260	Ogden-Clearfield, UT
51113	MADISON	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	16620	Charleston, WV
54043	LINCOLN	16620	Charleston, WV
54057	MINERAL	19060	Cumberland, MD-WV
55069	LINCOLN	48140	Wausau-Weston, WI
72001	ADJUNTAS	38660	Ponce, PR
72055	GUANICA	49500	Yauco, PR
72081	LARES	10380	Aguadilla-Isabela, PR
72083	LAS MARIAS	32420	Mayagüez, PR
72141	UTUADO	10380	Aguadilla-Isabela, PR

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We are proposing that the wage data for all hospitals located in the counties listed here would now be considered when calculating their respective State's rural wage index. We further refer readers to section III.G.6 of the preamble of this proposed rule for a discussion of the 5 percent cap policy. We believe that this policy, which caps any reduction in wage index values at 5 percent of the hospital's prior year wage index value, provides an adequate transition to mitigate sudden negative financial impacts due to the adoption of wage index policies, including the adoption of revised OMB labor market delineations.

We are also proposing revisions to the list of counties deemed urban under section 1886(d)(8)(B) of the Act, which will affect a number the hospitals located in these proposed rural counties. We note that we are proposing to add 17 of the 53 counties listed here to the list of ''Lugar'' counties whose hospitals, pursuant to 1886(d)(8)(B), are deemed to be in an urban area. We refer readers to section III.F.4.b for further discussion.

In addition, we note the provisions of § 412.102 of our regulations would continue to apply with respect to determining DSH payments. Specifically, in the first year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals one third of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.

5. Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the revised OMB statistical area delineations (based upon OMB Bulletin No. 23–01) beginning in FY 2025. Analysis of these OMB statistical area delineations shows that a total of 54 counties (and county equivalents) and 24 hospitals that were located in rural areas would be located in urban areas under the revised OMB delineations. The following chart lists the 54 rural counties that would be urban if we finalize our proposal to implement the revised OMB delineations.

COUNTIES THAT WOULD GAIN URBAN STATUS			
FIPS County Code	County Name	Proposed FY 2025 CBSA	Proposed FY 2025 CBSA Name
01087	MACON	12220	Auburn-Opelika, AL
01127	WALKER	13820	Birmingham, AL
12133	WASHINGTON	37460	Panama City-Panama City Beach, FL
13187	LUMPKIN	12054	Atlanta-Sandy Springs-Roswell, GA
15005	KALAWAO	27980	Kahului-Wailuku, HI
17053	FORD	16580	Champaign-Urbana, IL
17127	MASSAC	37140	Paducah, KY-IL
18159	TIPTON	26900	Indianapolis-Carmel-Greenwood, IN
18179	WELLS	23060	Fort Wayne, IN
20021	CHEROKEE	27900	Joplin, MO-KS
21007	BALLARD	37140	Paducah, KY-IL
21039	CARLISLE	37140	Paducah, KY-IL
21127	LAWRENCE	26580	Huntington-Ashland, WV-KY-OH
21139	LIVINGSTON	37140	Paducah, KY-IL
21145	MC CRACKEN	37140	Paducah, KY-IL
21179	NELSON	31140	Louisville/Jefferson County, KY-IN
22053	JEFFRSON DAVIS	29340	Lake Charles, LA

COUNTIES THAT WOULD GAIN URBAN STATUS			
FIPS County Code	**County Name**	**Proposed FY 2025 CBSA**	**Proposed FY 2025 CBSA Name**
22083	RICHLAND	33740	Monroe, LA
26015	BARRY	24340	Grand Rapids-Wyoming-Kentwood, MI
26019	BENZIE	45900	Traverse City, MI
26055	GRAND TRAVERSE	45900	Traverse City, MI
26079	KALKASKA	45900	Traverse City, MI
26089	LEELANAU	45900	Traverse City, MI
27133	ROCK	43620	Sioux Falls, SD-MN
28009	BENTON	32820	Memphis, TN-MS-AR
28123	SCOTT	27140	Jackson, MS
30007	BROADWATER	25740	Helena, MT
30031	GALLATIN	14580	Bozeman, MT
30043	JEFFERSON	25740	Helena, MT
30049	LEWIS AND CLARK	25740	Helena, MT
30061	MINERAL	33540	Missoula, MT
32019	LYON	39900	Reno, NV
37125	MOORE	38240	Pinehurst-Southern Pines, NC
38049	MCHENRY	33500	Minot, ND
38075	RENVILLE	33500	Minot, ND
38101	WARD	33500	Minot, ND
39007	ASHTABULA	17410	Cleveland, OH
39043	ERIE	41780	Sandusky, OH
41013	CROOK	13460	Bend, OR
41031	JEFFERSON	13460	Bend, OR
42073	LAWRENCE	38300	Pittsburgh, PA
45087	UNION	43900	Spartanburg, SC
46033	CUSTER	39660	Rapid City, SD
47081	HICKMAN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	18580	Corpus Christi, TX
48035	BOSQUE	47380	Waco, TX
48079	COCHRAN	31180	Lubbock, TX
48169	GARZA	31180	Lubbock, TX
48219	HOCKLEY	31180	Lubbock, TX
48323	MAVERICK	20580	Eagle Pass, TX
48407	SAN JACINTO	26420	Houston-Pasadena-The Woodlands, TX
51063	FLOYD	13980	Blacksburg-Christiansburg-Radford, VA
51181	SURRY	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	VERNON	29100	La Crosse-Onalaska, WI-MN

We are proposing that when calculating the area wage index, the wage data for hospitals located in these counties would be included in their new respective urban CBSAs. We also note that due to the proposed adoption of the revised OMB delineations, some CAHs that were previously located in rural areas may be located in urban areas. The regulations at §§ 412.103(a)(6) and 485.610(b)(5) provide affected CAHs with a two-year transition period that begins from the date the redesignation becomes effective. The affected CAHs must

reclassify as rural during this transition period in order to retain their CAH status after the two-year transition period ends. We refer readers to the FY 2015 IPPS/LTCH final rule (79 FR 50162 through 50163) for further discussion of the two-year transition period for CAHs. We also note that special statuses limited to hospitals located in rural areas (such as MDH or SCH status) may be terminated if hospitals are located in proposed urban counties. In these cases, affected hospitals should apply for rural reclassification status under § 412.103 prior to October 1, 2024 to ensure no disruption in status.

6. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to a new or existing urban CBSA under our proposal to adopt the new OMB delineations.

In some cases, the change in CBSA would extend only to a change in name. Revised CBSA names can be found in Table 3 of the addendum of the proposed rule. In other cases, the CBSA number also would change. For these CBSAs, the list of constituent urban counties in FY 2024 and FY 2025 would be the same (except in instances where an urban county became rural, or a rural county became urban; as discussed in the previous section). The following table lists the CBSAs where, under the proposed delineations, the CBSA name and number would change but the constituent counties would not change (not including instances where an urban county became rural, or a rural county became urban).

URBAN AREAS WITH CBSA NAME AND NUMBER CHANGE			
FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
45540	The Villages, FL	48680	Wildwood-The Villages, FL
23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
15680	California-Lexington Park, MD	30500	Lexington Park, MD
35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
17460	Cleveland-Elyria, OH	17410	Cleveland, OH

In some cases, all of the urban counties from a FY 2024 CBSA would be moved and subsumed by another CBSA in FY 2025. The following table lists the CBSAs that, under the proposed delineations, would be subsumed by an another CBSA.

URBAN AREAS BEING SUBSUMED BY ANOTHER CBSA			
FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
31460	Madera, CA	23420	Fresno, CA
36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
41900	San Germán, PR	32420	Mayagüez, PR

In other cases, if we adopt the revised OMB delineations, some counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. For example, Calvert County, MD would move from the current CBSA 12580 (Washington-Arlington-Alexandria, DC-VA-MD-WV) into proposed CBSA 30500 (Lexington Park, MD). The other constituent counties of CBSA 12580 would be split into urban CBSAs 47664 (Washington, DC-MD) and 11694 (Arlington-Alexandria-Reston, VA-WV). The following chart lists the urban counties that would split off from one urban CBSA and move to a newly proposed or modified urban CBSA if we adopt the revised OMB delineations.

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA					
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	**Proposed** FY 2025 CBSA Name
11001	THE DISTRICT	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
12053	HERNANDO	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12057	HILLSBOROUGH	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12101	PASCO	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12103	PINELLAS	45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL
13013	BARROW	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13015	BARTOW	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13035	BUTTS	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13045	CARROLL	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13057	CHEROKEE	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13063	CLAYTON	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13067	COBB	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13077	COWETA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13085	DAWSON	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13089	DE KALB	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13097	DOUGLAS	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13113	FAYETTE	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13117	FORSYTH	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13121	FULTON	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13135	GWINNETT	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13143	HARALSON	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13149	HEARD	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13151	HENRY	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13159	JASPER	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13199	MERIWETHER	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13211	MORGAN	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13217	NEWTON	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13223	PAULDING	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13227	PICKENS	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13231	PIKE	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13247	ROCKDALE	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13255	SPALDING	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA					
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	**Proposed** FY 2025 CBSA Name
13297	WALTON	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
17097	LAKE	29404	Lake County-Kenosha County, IL-WI	29404	Lake County, IL
21163	MEADE	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN
22103	ST. TAMMANY	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA
24009	CALVERT	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD
24017	CHARLES	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24033	PRINCE GEORGES	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24037	ST. MARYS	15680	California-Lexington Park, MD	30500	Lexington Park, MD
25015	HAMPSHIRE	44140	Springfield, MA	11200	Amherst Town-Northampton, MA
34009	CAPE MAY	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
37019	BRUNSWICK	34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	48900	Wilmington, NC
39123	OTTAWA	45780	Toledo, OH	41780	Sandusky, OH
47057	GRAINGER	34100	Morristown, TN	28940	Knoxville, TN
51013	ARLINGTON	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51043	CLARKE	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51047	CULPEPER	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51059	FAIRFAX	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51061	FAUQUIER	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51107	LOUDOUN	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51153	PRINCE WILLIAM	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51157	RAPPAHANNOCK	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51177	SPOTSYLVANIA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51179	STAFFORD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51187	WARREN	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51510	ALEXANDRIA CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51600	FAIRFAX CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51610	FALLS CHURCH CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51630	FREDERICKSBURG CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51683	MANASSAS CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51685	MANASSAS PARK CITY	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
53061	SNOHOMISH	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA
54037	JEFFERSON	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
55059	KENOSHA	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI
72023	CABO ROJO	41900	San Germán, PR	32420	Mayagüez, PR
72059	GUAYANILLA	49500	Yauco, PR	38660	Ponce, PR
72079	LAJAS	41900	San Germán, PR	32420	Mayagüez, PR
72111	PENUELAS	49500	Yauco, PR	38660	Ponce, PR

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA					
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	**Proposed** FY 2025 CBSA Name
72121	SABANA GRANDE	41900	San Germán, PR	32420	Mayagüez, PR
72125	SAN GERMAN	41900	San Germán, PR	32420	Mayagüez, PR
72153	YAUCO	49500	Yauco, PR	38660	Ponce, PR

If hospitals located in these counties move from one CBSA to another under the revised OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. We refer readers to section III.F.3. of the preamble of this proposed rule for discussion of our proposals to address the reassignment of MGCRB wage index reclassifications for hospitals currently assigned to these modified CBSAs.

7. Transition

Overall, we believe implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual current costs of labor in a given area. However, we recognize that some hospitals would experience decreases in wage index values as a result of our proposed implementation of the new labor market area delineations. We also realize that some hospitals would have higher wage index values due to our proposed implementation of the new labor market area delineations.

In the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. When adopting new OMB delineations based on the decennial census for the 2005 and 2015 wage indexes, we applied a 3-year transition for urban hospitals that became rural under the new delineations and a 50/50 blended wage index adjustment for all hospitals that would experience any decrease in their actual payment wage index (69 FR 49032 through 49034 and 79 FR 28060 through 28062).

In connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, which included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses, we adopted a policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020 (85 FR 58753 through 58755). Given the unprecedented nature of the COVID–19 public health emergency (PHE), we adopted a policy in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165) to apply an extended transition to the FY 2022 wage index for hospitals affected by the transition in FY 2021 to mitigate significant negative impacts of, and provide additional time for hospitals to adapt to, the CMS decision to adopt the revised OMB delineations. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), under the authority at sections 1886(d)(3)(E) and 1886(d)(5)(I)(i) of the Act, we finalized a policy for FY 2023 and subsequent years to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

We believe that this permanent cap policy, reflected at 42 CFR 412.64(h)(7) and discussed in section in III.G.6. of the preamble of this proposed rule, sufficiently mitigates any large negative impacts of adopting the new delineations. As we stated when finalizing the permanent 5-percent cap policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we further considered the comments we received during the FY 2022 rulemaking recommending a permanent 5 percent cap policy to prevent large year-to-year variations in wage index values as a means to reduce overall volatility for hospitals. We do not believe any additional transition period is necessary considering that the current cap on wage index decreases, which was not in place when we implemented the decennial census updates in FY 2005 and FY 2015, ensures that a hospital's wage index would not be less than 95 percent of its final wage index for the prior year.

C. Worksheet S–3 Wage Data for the Proposed FY 2025 Wage Index

1. Cost Reporting Periods Beginning in FY 2021 for FY 2025 Wage Index

The proposed FY 2025 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2021 (the FY 2024 wage indexes were based on data from cost reporting periods beginning during FY 2020).

The FY 2025 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

Consistent with the wage index methodology for FY 2024, the proposed wage index for FY 2025 excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2025 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs), because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). Similar to our treatment of CAHs, as discussed below, we are proposing to exclude Rural Emergency Hospitals (REHs) from the wage index.

For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

2. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

3. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2025 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2025) for cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021. For wage index purposes, we refer to cost reports beginning on or after October 1, 2020, and before October 1, 2021, as the ''FY 2021 cost report,'' the ''FY 2021 wage data,'' or the ''FY 2021 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2025 wage index includes FY 2021 data submitted to us as of January 26, 2024. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

Consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the wage index include generally using the most current data and information available, which is usually data on a 4-year lag (for example, for the FY 2023 wage index we used cost report data from FY 2019). We stated in the FY 2023 IPPS/LTCH final rule (87 FR 48994) that we will be looking at the differential effects of the COVID–19 PHE on the audited wage data in future fiscal years. We also stated we plan to review the audited wage data, and the impacts of the COVID–19 PHE on such data and evaluate these data for future rulemaking. For the FY 2025 wage index, the best available data typically would be from the FY 2021 wage data.

In considering the impacts of the COVID–19 PHE on the FY 2021 wage data, we compared that data with recent historical data. Based on pre reclassified wage data, the changes in the wage data from FY 2020 to FY 2021 show the following compared to the annual changes for the most recent 3 fiscal year periods (that is, FY 2017 to FY 2018, FY 2018 to FY 2019 and FY 2019 to FY 2020):

- Approximately 91 percent of hospitals have an increase in their average hourly wage (AHW) from FY 2020 to FY 2021 compared to a range of 76–86 percent of hospitals for the most recent 3 fiscal year periods.
- Approximately 97 percent of all CBSA AHWs are increasing from FY 2020 to FY 2021 compared to a range of 84–91 percent of all CBSAs for the most recent 3 fiscal year periods.
- Approximately 51 percent of all urban areas have an increase in their area wage index from FY 2020 to FY 2021 compared to a range of 36–43 percent of all urban areas for the most recent 3 fiscal year periods.
- Approximately 55 percent of all rural areas have an increase in their area wage index from FY 2020 to FY 2021 compared to a range of 31–46 percent of all rural areas for the most recent 3 fiscal year periods.
- The unadjusted national average hourly wage increased by a range of 2.4–5.4 percent per year from FY 2017–FY 2020. For FY 2021, the unadjusted national average hourly increased by 8.7 percent from FY 2020.

Similar to the FY 2024 wage index, it is not readily apparent even if the comparison with the historical trends had indicated greater differences at a national level in this context, how any changes due to the COVID–19 PHE *differentially* impacted the wages paid by individual hospitals. Furthermore, even if changes due to the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data to account for the effects of the COVID–19 PHE.

Lastly, we also note that we have not identified any significant issues with the FY 2021 wage data itself in terms of our audits of this data. As usual, the data was audited by the Medicare Administrative Contractors (MACs), and there were no significant issues reported across the data for all hospitals.

Taking all of these factors into account, we believe the FY 2021 wage data is the best available wage data to use for FY 2025 and are proposing to use the FY 2021 wage data for FY 2025.

We welcome comment from the public with regard to the FY 2021 wage data. We note, AHW data by provider and CBSA, including the data upon which the comparisons provided above are based, is available in our Public Use Files released with each proposed and final rule each fiscal year. The Public Use Files for the respective FY Wage Index Home Page can be found on the Wage Index Files web page at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files.*

We requested that our MACs revise or verify data elements that resulted in specific edit failures. For the proposed FY 2025 wage index, we identified and excluded 69 providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2025 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their verification of questionable data elements and to transmit any changes to the wage data no later than March 20, 2024.

In constructing the proposed FY 2025 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2021, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed rule, we removed 8 hospitals that converted to CAH status on or after January 23, 2023, the cut-off date for

CAH exclusion from the FY 2024 wage index, and through and including January 24, 2024, the cut-off date for CAH exclusion from the FY 2025 wage index. We note, we also removed 2 hospitals that converted to CAH status prior to January 23, 2023.

The Consolidated Appropriations Act (CAA), 2021, was signed into law on December 27, 2020. Section 125 of Division CC (section 125) established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). (We refer the reader to the CMS website at *https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulations/hospitals/rural-emergency-hospitals* for additional information on REHs.) In doing so, section 125 amended section 1861(e) of the Act, which provides the definition of a hospital and states that the term ''hospital'' does not include, unless the context otherwise requires, a critical access hospital (as defined in subsection (mm)(1)) or a rural emergency hospital (as defined in subsection (kkk)(2)). Section 125 also added section 1861(kkk) to the Act, which sets forth the requirements for REHs. Per section 1861(kkk)(2) of the Act, one of the requirements for an REH is that it does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)). Similar to CAHs, we believe hospitals that have subsequently converted to REH status should be removed from the wage index calculation, because they are a separately certified Medicare provider type and are not comparable to other short-term, acute care hospitals as they do not provide inpatient hospital services. For FY 2025, we are proposing to treat REHs the same as CAHs and exclude 15 REHs from the wage index. Accordingly, similar to our policy on CAHs, any hospital that is designated as a REH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. In summary, we calculated the FY 2025 wage index using the Worksheet S–3, Parts II and III wage data of 3,075 hospitals.

For the proposed FY 2025 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2025 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 27 multicampus hospitals. The following chart lists the multicampus hospitals by CMS certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of Main Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Main Campus	CCN of Sub Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Sub Campus
050121	0.86	05B121	0.14
070010	0.86	07B010	0.14
070022	0.99	07B022	0.01
100029	0.52	10B029	0.48
100167	0.91	10B167	0.09
140010	0.81	14B010	0.19
220074	0.89	22B074	0.11
310069	0.18	31B069	0.82
330103	0.67	33B103	0.33
330195	0.89	33B195	0.11
330214	0.76	33B214	0.24
330234	0.79	33B234	0.21
340115	0.82	34B115	0.18
360020	0.98	36B020	0.02
390115	0.83	39B115	0.17
390142	0.83	39B142	0.17
450033	0.90	45B033	0.10
450330	0.96	45B330	0.04
460051	0.78	46B051	0.22
510022	0.94	51B022	0.06
520009	0.71	52B009	0.29
520030	0.97	52B030	0.03
670062	0.74	67B062	0.26
670102	0.88	67B102	0.12
670107	0.69	67B107	0.31
670116	0.66	67B116	0.34

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other variable digits in the CCN.

4. Process for Requests for Wage Index Data Corrections

a. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2025 wage index were made available on May 23, 2023, through the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-wage-index-home-page.* We subsequently identified some providers that were inadvertently omitted from the FY 2025 preliminary Worksheet S–3 wage data file originally posted on May 23, 2023. Therefore, on July 12, 2023, we posted an updated FY 2025 preliminary Worksheet S–3 wage data file to include these missing providers. In addition, the Calendar Year (CY) 2022 occupational mix survey data was made available on July 12, 2023, through the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-wage-index-home-page.* On August 14, 2023, we posted an updated CY 2022 Occupational Mix survey data file that includes survey data for providers that were inadvertently omitted from the file posted on July 12, 2023.

On January 31, 2024, we posted a public use file (PUF) at *https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-wage-index-home-page* containing FY 2025 wage index data available as of January 31, 2024. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2020, through September 30, 2021; that is, FY 2021 wage data), a tab with the occupational mix data (which includes data from the CY 2022 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data

of hospitals deleted from the January 31, 2024 wage data PUF, and a tab containing the CY 2022 occupational mix data of the hospitals deleted from the January 31, 2024 occupational mix PUF. In a memorandum dated January 31, 2024, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 31, 2024, wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2025 Hospital Wage Index Development Time Table available at *https://www.cms.gov/files/document/fy2025-hospital-wage-index-development-timetable.pdf.*

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums.*

In a memorandum dated May 4, 2023, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2022 occupational mix survey data files posted on May 23, 2023, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 23, 2023, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 1, 2023. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs.

November 3, 2023 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2024. CMS published the wage index PUFs that included hospitals' revised wage index data on January 31, 2024. Hospitals had until February 16, 2024, to submit requests to the MACs to correct errors in the January 31, 2024, PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 31, 2024, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must have been received by the MAC by the February deadline (that is, by February 16, 2024, for the FY 2025 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 20, 2024. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) is April 3, 2024. Data that were incorrect in the preliminary or January 31, 2024, wage index data PUFs, but for which no correction request was received by the February 16, 2024, deadline, are not considered for correction at this stage. In addition, April 3, 2024, is the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 31, 2024, PUF and at least 14 calendar days prior to April 3, 2024 (that is, March 20, 2024), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 3, 2024, for the FY 2025 wage index). We refer readers to the FY 2025 Hospital Wage Index Development Time Table for complete details. Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-wage-index-home-page.* Table 2 associated with the proposed rule contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2025 wage index, which was constructed from FY 2021 data. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by early February 2024.

We plan to post the final wage index data PUFs on April 29, 2024, on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2024-wage-index-home-page.* The April 2024 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process (the process for disputing revisions submitted to CMS by the MACs by March 20, 2024, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier), as previously described.

After the release of the April 2024 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 20, 2024.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 31, 2024, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2024 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 29, 2024. May 29, 2024, is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 3, 2024 (that is, March 21, 2024), and at least 14 calendar days prior to May 29, 2024 (that is, May 15, 2024), that did not arise from a hospital's request for

revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 29, 2024 (that is, May 16, 2024), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2025 Hospital Wage Index Development Time Table posted on the CMS website at *https://www.cms.gov/files/document/fy2025-hospital-wage-index-development-timetable.pdf,* the May appeals are required to be submitted to CMS through an online submission process or through email. We refer readers to the FY 2025 Hospital Wage Index Development Time Table for complete details.

Verified corrections to the wage index data received timely (that is, by May 29, 2024) by CMS and the MACs will be incorporated into the final FY 2025 wage index, which will be effective October 1, 2024.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2025 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2024, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2025 wage index by August 2024, and the implementation of the FY 2025 wage index on October 1, 2024. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 29, 2024, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 29, 2024, for the FY 2025 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised § 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 29, 2024, deadline for the FY 2025 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 29, 2024 deadline for the FY 2025 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in § 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

b. Process for Data Corrections by CMS After the January 31 Public Use File (PUF)

The process set forth with the wage index timetable discussed in section III.C.4. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through

49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 31 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data the need for which may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error, and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 31 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency in instances where CMS makes data corrections after the January 31 PUF and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2025 Hospital Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

D. Method for Computing the Proposed FY 2025 Unadjusted Wage Index

The method used to compute the proposed FY 2025 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758–58761), and we are not proposing any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2025, these were data from cost reports for cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021). In addition, we included data from hospitals that had cost reporting periods beginning prior to the October 1, 2020 begin date and extending into FY 2021 but that did not have any cost report with a begin date on or after October 1, 2020 and before October 1, 2021. We include this data because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as data applicable to the fiscal year wage data being used to compute the wage index for those hospitals. We note that, if a hospital had more than one cost reporting period beginning during FY 2021 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use

the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula:

(Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43).

We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following:

(Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − ;(Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).

- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2020, through April 15, 2022, for private industry hospital workers from data obtained from the Bureau of Labor Statistics' (BLS') Office of Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2025. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSAs' wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306,). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the proposed FY 2025 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website), which contains the area wage indexes, we include a footnote to indicate to which CBSA this policy applies. This CBSA's wage index would be calculated as described, based on the FY 2020 IPPS/LTCH PPS final rule methodology (84 FR 42305). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this proposed rule.

We refer readers to section II. of the Appendix of the proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the ECI for compensation for each 30-day increment from October 14, 2020, through April 15, 2022, for private industry hospital workers from the BLS' Office of Compensation and Working Conditions data. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2025. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2020	11/15/2020	1.06153
11/14/2020	12/15/2020	1.05922
12/14/2020	01/15/2021	1.05683
01/14/2021	02/15/2021	1.05414
02/14/2021	03/15/2021	1.05116
03/14/2021	04/15/2021	1.04786
04/14/2021	05/15/2021	1.04421
05/14/2021	06/15/2021	1.04023
06/14/2021	07/15/2021	1.03606
07/14/2021	08/15/2021	1.03183
08/14/2021	09/15/2021	1.02755
09/14/2021	10/15/2021	1.02318
10/14/2021	11/15/2021	1.01870
11/14/2021	12/15/2021	1.01409
12/14/2021	01/15/2022	1.00941
01/14/2022	02/15/2022	1.00471
02/14/2022	03/15/2022	1.00000
03/14/2022	04/15/2022	0.99537

For example, the midpoint of a cost reporting period beginning January 1, 2021, and ending December 31, 2021, is June 30, 2021. An adjustment factor of 1.03606 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of Division O, Title VI (section 601) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2025, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously discussed methodology, the proposed FY 2025 unadjusted national average hourly wage is the following:

Proposed FY 2025 Unadjusted National Average Hourly Wage	$54.80

E. Proposed Occupational Mix Adjustment to the FY 2025 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of New 2022 Medicare Wage Index Occupational Mix Survey for the FY 2025 Wage Index

Section 304(c) of Appendix F, Title III of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each

short-term, acute care hospital participating in the Medicare program and to measure the earnings and paid hours of employment for such hospitals by occupational category. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25402 through 25403) and final rule (86 FR 45173), we collected data in 2019 to compute the occupational mix adjustment for the FY 2022, FY 2023, and FY 2024 wage indexes. A new measurement of occupational mix is required for FY 2025.

The FY 2025 occupational mix adjustment is based on a new calendar year (CY) 2022 survey. Hospitals were required to submit their completed 2022 surveys (Form CMS–10079, OMB Number 0938–0907, expiration date January 31, 2026) to their MACs by July 1, 2023. The preliminary, unaudited CY 2022 survey data were posted on the CMS website on July 12, 2023. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2025 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

Consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the occupational mix adjustment include generally using the most current data and information available, which is usually occupational mix data on a 3-year lag in the first year of the use of the occupational mix survey (for example, for the FY 2022 wage index we used occupational mix data from 2019; we also used this data for the FY 2023 and FY 2024 wage indexes). In the FY 2024 IPPS/LTCH final rule (88 FR 58969–58970), one commenter had concerns that the 2025 occupational mix data may be skewed due to the COVID–19 PHE, and we stated that we plan to assess the CY 2022 Occupational Mix Survey data in the FY 2025 IPPS proposed rule.

Based on pre-reclassified wage data, we computed the unadjusted and adjusted wage indexes for FY 2025 using the 2022 occupational mix survey data. We then measured the increases and decreases by CBSA as a result of the 2022 occupational mix survey data. We compared this table to the same table for the FY 2024 wage indexes, which used the 2019 occupational mix data, as well as the FY 2021 wage indexes, which used the 2016 occupational mix data. This table demonstrates the impact of the occupational mix adjusted wage data compared to unadjusted wage data for the most recent three occupational mix surveys using the 2022 survey data compared to the 2019 survey data and the 2016 survey data. That is, it shows whether hospitals' wage indexes will increase or decrease under the 2022 survey data as compared to the most recent years using the prior 2019 survey data and 2016 survey data respectively.

Comparison of the Occupational Mix Adjusted Wage Indexes to the Unadjusted Wage Indexes by CBSA			
	CY 2016 Occupational Mix Survey (Using FY 2021 Wage Data)	CY 2019 Occupational Mix Survey (Using FY 2024 Wage Data)	CY 2022 Occupational Mix Survey (Using FY 2025 Wage Data)
Number of Urban Areas Wage Index Increasing	238 (57.77%)	231 (56.07%)	248 (60.19%)
Number of Rural Areas Wage Index Increasing	20 (42.55%)	27 (57.45%)	28 (59.57%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	114 (27.67%)	125 (30.34%)	148 (35.92%)
Number of Urban Areas Wage Index Increasing by 5 percent or More	7 (1.7%)	5 (1.21%)	6 (1.46%)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	9 (19.15%)	12 (25.53%)	17 (36.17%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0%)	0 (0%)	0 (0%)
Number of Urban Areas Wage Index Decreasing	173 (41.99%)	179 (43.45%)	163 (39.56%)
Number of Rural Areas Wage Index Decreasing	26 (55.32%)	20 (42.55%)	19 (40.43%)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	80 (19.42%)	78 (18.93%)	85 (20.63%)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	1 (0.24%)	3 (0.73%)	1 (0.24%)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8 (17.02%)	8 (17.02%)	6 (12.77%)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)	0 (0%)	0 (0%)
Largest Positive Impact for an Urban Area	6.46%	7.17%	8.43%
Largest Positive Impact for a Rural Area	3.89%	4.07%	3.85%
Largest Negative Impact for an Urban Area	-5.91%	-5.56%	-6.16%
Largest Negative Impact for a Rural Area	-1.79%	-2.56%	-4.17%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1 (0.24%)	2 (0.49%)	1 (0.24%)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	1 (2.13%)	0 (0%)	0 (0%)

Based on the table, increases and decreases by CBSA are alike across each year of occupational mix data. For example, 60.19 percent of urban areas' wage indexes are increasing in FY 2025 due to the CY 2022 occupational mix data compared to 56.07 percent in FY 2024 using CY 2019 occupational mix data. Similarly, 59.57 percent of rural areas' wage indexes are increasing in FY 2025 due to the CY 2022 occupational mix data compared to 57.45 percent in FY 2024 using CY 2019 occupational mix data. We also note that similar to the wage data, it is not readily apparent, even if the comparison with the historical trends had indicated greater differences by CBSA in this context, how any changes due to the COVID–19 PHE differentially impacted the occupational mix adjusted wages paid in each CBSA. Furthermore, even if hypothetically changes due to the COVID–19 PHE did differentially impact the occupational mix adjusted wage index over time, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data accordingly.

Lastly, we also note that we have not identified any significant issues with the 2022 occupational mix data itself in terms of our audits of this data. As usual, the data was audited by the MACs, and there were no significant issues reported across the data for all hospitals.

Taking all these factors into account, we believe the CY 2022 occupational mix data is the best available data to use for FY 2025 and are proposing to use the CY 2022 occupational mix data for FY 2025.

2. Calculation of the Occupational Mix Adjustment for FY 2025

For FY 2025, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2025 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on

Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2025 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2025 wage index. For the proposed FY 2025 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,075 hospitals, and we used the occupational mix surveys of 2,950 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 96 percent (2,950/3,075). For the proposed FY 2025 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2025 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2025 Occupational Mix Adjusted National Average Hourly Wage	$54.73

3. Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2025 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2025, we are applying the occupational mix adjustment to 100 percent of the FY 2025 wage index. We calculated the occupational mix adjustment using data from the 2022 occupational mix survey, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582–51586).

Based on the 2022 occupational mix survey data, the proposed FY 2025 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$60.40
National LPN and Surgical Technician	$35.01
National Nurse Aide, Orderly, and Attendant	$23.53
National Medical Assistant	$23.11
National Nurse Category	$50.17

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2022 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	46%
National Percentage of Hospital Employees in the All Other Occupations Category	54%

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

F. Hospital Redesignations and Reclassifications

The following sections III.F.1 through III.F.4 discuss revisions to the wage index based on hospital redesignations and reclassifications. Specifically, hospitals may have their geographic area changed for wage index payment by applying for urban to rural reclassification under section 1886(d)(8)(E) of the Act (implemented at § 412.103), reclassification by the Medicare Geographic Classification Review Board (MGCRB) under section 1886(d)(10) of the Act, Lugar status redesignations under section 1886(d)(8)(B) of the Act, or a combination of the foregoing.

1. Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act, Implemented at § 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at § 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act (such hospitals are referred to herein as ''§ 412.103 hospitals''). The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977) for a review of our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004) to calculate the rural floor with the wage data of urban hospitals reclassifying to rural areas under § 412.103, and discussion of our modification to the calculation of the rural wage index and its implications for the rural floor.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at §§ 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under § 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain Sole Community Hospital (SCH), Rural Referral Center (RRC), or Medicare Dependent Hospital (MDH) status, or rural reclassification under § 412.103, independently or separately from its remote location(s), and vice versa. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012 and 49013), we added § 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS' longstanding policy to assign that remote location a wage index based on its own geographic area in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSAs on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a ''B'' in the 3rd position of the CCN. These remote locations of hospitals with § 412.103 rural reclassification status in a different CBSA are identified in Table 2, and hospitals should evaluate potential wage index outcomes for their remote location(s) when withdrawing or terminating MGCRB reclassification, or canceling § 412.103 rural reclassification status.

We also note that in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59038 through 59039), we changed the effective date of rural reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92, where eligibility for SCH classification depends on a hospital merger. Specifically, we finalized that in these circumstances, and subject to the hospital meeting the requirements set forth at § 412.92(b)(2)(vi), the effective date for rural reclassification will be the effective date set forth in § 412.92(b)(2)(vi).

Finally, we remind hospitals currently located in rural areas becoming urban under the proposed adoption of the revised OMB delineations in this proposed rule that if they have SCH, MDH, or RRC status, they may choose to apply for a § 412.103 urban to rural reclassification if qualifying criteria are met in order to maintain the SCH, MDH, or RRC status. We advise hospitals to evaluate their options and if desired, apply for § 412.103 urban to rural reclassification before the beginning of FY 2025, to avoid a lapse in SCH, MDH, or RRC status at the beginning of FY 2025 should we finalize our proposal to adopt the revised OMB delineations.

a. Proposed Update to Rural Criteria at § 412.103(a)(1)

Section 1886(d)(8)(E) of the Act describes criteria for hospitals located in urban areas to be treated as being located in a rural area of their state. The criterion at section 1886(d)(8)(E)(ii)(I) of the Act requires that the hospital be located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the **Federal Register** on February 27, 1992 (57 FR 6725)).

This condition is implemented in the regulation at § 412.103(a)(1), which currently states: ''the hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area codes, as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA), which is available via the ORHP website at: *http://www.ruralhealth.hrsa.gov* or from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Office of Rural Health Policy, 5600 Fishers Lane, Room 9A–55, Rockville, MD 20857.''

The Goldsmith Modification [136] was originally designed to identify rural census tracts located in Metropolitan counties for purposes of grant eligibility unrelated to the hospital IPPS but were incorporated by section 1886(d)(8)(E)(ii)(I) of the Act for

[136] Known as the ''Goldsmith Modification'' for its principal developer, Harold F. Goldsmith, this method is described in detail in the paper ''Improving the Operational Definition of ''Rural Areas'' for Federal Programs'' available at *https://www.ruralhealthinfo.org/pdf/improving-the-operational-definition-of-rural-areas.pdf.*

purposes related to the hospital wage index.

The Federal Office of Rural Health Policy (FORHP) (known as ORHP in § 412.103) later funded development of Rural-Urban Commuting Area (RUCA) codes via the U.S. Department of Agriculture's (USDA) Economic Research Service as the latest version of the Goldsmith Modification, described in a May 3, 2007 **Federal Register** notice (72 FR 24589), to address limitations of the original Goldsmith Modification. RUCAs, like the Goldsmith Modification, are based on a sub-county unit, the census tract, permitting a finer delineation of what constitutes rural areas inside Metropolitan areas (72 FR 24590). In that notice, HRSA stated it believes that the use of RUCAs allows more accurate targeting of resources intended for the rural population to determine programmatic eligibility for rural areas inside of Metropolitan counties. Using data from the Census Bureau, every census tract in the United States is assigned a RUCA code. In the May 3, 2007 **Federal Register**, HRSA stated that ORHP considers all census tracts with RUCA codes 4–10 to be rural, plus an additional 132 large area census tracts with RUCA codes 2 or 3 (72 FR 24591). They also stated that ORHP will continue to seek refinements in the use of RUCAs.

FORHP has since published a revised definition of eligibility for rural health grants for FY 2022 in a January, 12, 2021 **Federal Register** Notice (86 FR 2418 through 2420). Specifically, FORHP added Metropolitan Statistical Area (MSA) counties that contain no Urbanized Area (UA) [137] to the areas eligible for the rural health grant programs. FORHP did not remove any areas from the rural definition in the FY 2022 **Federal Register** Notice.

It has come to our attention that our current regulation text at § 412.103(a)(1) does not describe FORHP's expanded definition of a ''rural area'' from the FY 2022 **Federal Register** Notice. In addition, § 412.103(a)(1) contains a web link that is no longer active and requires updating. We believe the current rural definition used by FORHP for purposes of the rural health grant program constitutes ''the most recent modification of the Goldsmith Modification'' referred to in the statute, since the expanded definition of rural constitutes a refinement to the use of RUCA codes, which were developed as the latest version of the Goldsmith Modification. As stated in the FY 2022 **Federal Register** Notice (86 FR 2420), the expanded criteria reflect FORHP's desire to accurately identify areas that are rural in character using a data-driven methodology that relies on existing geographic identifiers and utilizes standard, national level data sources. We are therefore proposing to amend our regulation text at § 412.103(a)(1) to provide a reference to the most recent **Federal Register** notice issued by HRSA defining ''rural areas.'' In this way, there will be no need to update the Medicare regulations if FORHP develops a further modification of the Goldsmith Modification or if the weblink changes. FORHP has published the current link in the **Federal Register** notice (86 FR 2418–2420) along with the most recent revisions to the current complete rural definition, and it is available via the Rural Health Grants Eligibility Analyzer at *https://data.hrsa.gov/tools/rural-health.*

We are proposing to amend the regulation text at 412.103(a)(1) to read: the hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, using the Rural-Urban Commuting Area codes and additional criteria, as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA), which is available at the web link provided in the most recent **Federal Register** notice issued by HRSA defining rural areas.

b. Proposed Policy for Canceling § 412.103 Reclassifications of Terminated Providers

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49499 through 49500), CMS discussed its longstanding policy to terminate the § 1886(d)(10) MGCRB wage index reclassification status for hospitals with terminated CMS certification numbers (CCN). We determined that it would be appropriate to terminate the MGCRB reclassification status for these hospitals (with a limited exception for certain locations acquired by another hospital in a different CBSA), as the hospital may no longer be able to make timely and informed decisions regarding reclassification statuses.

At the time, we did not articulate a similar policy for hospitals reclassified as rural under § 412.103. While policies regarding MGCRB reclassification were adopted for purposes related to the hospital wage index, § 412.103 reclassifications may have broader implications. At the time the policy to terminate MGCRB reclassifications for hospitals with terminated CCNs was implemented, § 412.103 reclassifications were less common, and generally had negligible effects on State rural wage index values. Prior to FY 2024, as a result of various wage index value hold-harmless policies, discussed in detail in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58973–58974), § 412.103 hospital data rarely affected a state's final rural wage index value. Under the current policy first implemented in FY 2024, however, § 412.103 hospital data is only excluded from the rural wage index when indicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Hospitals reclassified under § 412.103 now impact the rural wage index value of most states. We refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 58973 through 58977) for discussion on how CMS finalized the current policy to include the wage index data for § 412.103 hospitals in more iterations of the rural wage index calculation. Furthermore, following the policy implemented in the April 21, 2016 interim final rule with comment period (IFC) (81 FR 23428 through 23438), which allowed hospitals to maintain dual § 412.103 and MGCRB reclassification status, the number of rural reclassifications has grown significantly. We now believe it is appropriate to propose a policy regarding terminated or ''tied-out'' hospitals, effective for FY 2025, to address our concerns regarding the impacts these hospitals would have on rural wage index values. Therefore, we are proposing that § 412.103 reclassifications will be considered cancelled for the purposes of calculating area wage index for any hospital with a CCN listed as terminated or ''tied-out'' as of the date that the hospital ceased to operate with an active CCN. We propose to obtain and review the best available CCN termination status lists as of the § 412.103(b)(6) ''lock-in'' date (60 days after the proposed rule for the FY is displayed in the **Federal Register**). The lock-in date is used to determine whether a hospital has been approved for § 412.103 reclassification in time for that status to be included in the upcoming year's wage index development. We believe using this date for evaluating CCN terminations would be consistent with the wage index development timeline.

As stated previously, § 412.103 reclassification may have other implications for hospital status and payment. Hospitals may obtain rural reclassification for several reasons, such as in order to convert to a Critical Access Hospital (CAH), or to obtain Sole-Community Hospital (SCH) status.

[137] UAs are defined by the Census Bureau as densely settled areas with a total population of at least 50,000 people (86 FR 2418).

Eligibility requirements for Rural Emergency Hospital (REH) qualification under section 1861(kkk)(3) of the Act included a reference to reclassification under section 1886(d)(8)(E) (implemented by § 412.103). We note that our proposal to consider § 412.103 reclassifications cancelled for the purposes of calculating area wage index for any hospital with a CCN listed as terminated or ''tied-out'' is not intended to alter or affect the qualification for such statuses or to have other effects unrelated to hospital wage index calculations. The rural reclassification status would remain in effect for any period that the original PPS hospital remains in operation with an active CCN. For REH qualification requirement purposes, this would include the date of enactment of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which was December 27, 2020. We believe this policy provides consistency and predictability in wage index values.

2. General Policies and Effects of MGCRB Reclassification and Treatment of Dual Reclassified Hospitals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under § 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under § 412.103 from the calculation of the rural floor, but we reverted to the pre-FY 2020 policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004). Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of § 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. Prior to FY 2024, we excluded hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016 IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For FY 2024 and subsequent years, we refer readers to section III.G.1 of the preamble of the FY 2024 IPPS/LTCH PPS final rule for discussion of our proposal to include hospitals with a § 412.103 redesignation that also have an active MGCRB reclassification to another area in the calculation of the reclassified rural wage index (88 FR 58971 through 58977).

a. Proposed Revision To Allow § 412.103 Hospitals To Use Geographic Area or Rural Area for Reclassification

On May 10, 2021, we published an interim final rule with comment period (IFC) in the **Federal Register** (86 FR 24735 through 24739) that included provisions amending our regulations to allow hospitals with a rural redesignation to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. We revised our regulation so that the redesignated rural area, and not the hospital's geographic urban area, is considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). Similarly, we revised the regulations to consider the redesignated rural area, and not the geographic urban area, as the area a § 412.103 hospital is located in for purposes of applying the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the pre-reclassified average hourly wage for the area in which the hospital is located. Effective for reclassification applications due to the MGCRB for reclassification beginning in FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the State's rural area as the area in which the hospital is located. We refer readers to the May 10, 2021 IFC (86 FR 24735 through 24739) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45187 through 45190), in which we finalized the May 10, 2021 IFC, for a full discussion of these policies.

In a comment on the May 10, 2021 IFC (86 FR 24735 through 24739), a commenter noted that the IFC states that a hospital reclassified under § 412.103 could potentially reclassify to any area with a pre-reclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the State for purposes of the regulation at § 412.230(a)(5)(i). The commenter asserted that CMS' use of the word ''could'' in this context seems to suggest that CMS would allow the hospital to use either its home average hourly wage or the rural average hourly wage for purposes of the regulation at § 412.230(a)(5)(i). The commenter suggested that CMS allow both comparison options, because the rural average hourly wage may occasionally be higher than the hospital's home urban area's average hourly wage.

In response, we clarified that the commenter's interpretation of our policy is correct. We stated that while the court's decision *in Bates County Memorial Hospital* v. *Azar* requires CMS to permit hospitals to reclassify to any area with a pre-reclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the state, we do not believe that we are required to limit hospitals from using their geographic home area for purposes of the regulation at § 412.230(a)(5)(i). Therefore, we clarified that we would allow hospitals to reclassify to an area with an average hourly wage that is higher than the average hourly wage of either the hospital's geographic home area or the rural area (86 FR 45189).

While we clarified our policy in response to the aforementioned comment, the regulation text was not similarly clarified to reflect this policy inadvertently. We are therefore proposing to revise the regulation text at § 412.230(a)(5)(i) to reflect our policy clarified in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45189). While it has been CMS' policy to allow a § 412.103 hospital to use either its geographic area or the rural area of the State for purposes of § 412.230(a)(5)(i), we believe that synchronizing the regulation text with our policy clarified in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45189) is necessary for consistency and to reduce unnecessary Administrative appeals.

Specifically, we are proposing to replace the phrase in the regulation at § 412.230(a)(5)(i) that reads ''in the rural area of the state'' with the phrase ''either in its geographic area or in the rural area of the state.'' Section 412.230(a)(5)(i) with this proposed revision would read: An individual hospital may not be redesignated to another area for purposes of the wage index if the pre-reclassified average hourly wage for that area is lower than the pre-reclassified average hourly wage for the area in which the hospital is located. An urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located either in its geographic area or in the rural area of the State for the purposes of this paragraph (a)(5)(i).

3. MGCRB Reclassification Issues for FY 2025

a. FY 2025 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. There are 610 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2025. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2025, hospitals reclassified beginning in FY 2023 or FY 2024 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 237 hospitals approved for wage index reclassifications in FY 2023 that will continue for FY 2025, and 316 hospitals approved for wage index reclassifications in FY 2024 that will continue for FY 2025. Of all the hospitals approved for reclassification for FY 2023, FY 2024, and FY 2025, 1,163 (approximately 32.5 percent) hospitals are in a MGCRB reclassification status for FY 2025 (with 248 of these hospitals reclassified back to their geographic location). We refer readers to Section III.F.3.b of this proposed rule for information on the effects of implementation of new OMB labor market area delineations on reclassified hospitals.

Under the regulations at § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. Please note that Section III.F.3.c. of this proposed rule contains a proposal to change the deadline for the withdrawal requests to 45 days from the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register.

For information about the current process for withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Applications for FY 2026 reclassifications are due to the MGCRB by September 1, 2024. This is also the current deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d) for the FY 2025 cycle.

Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2024 via the internet on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board.* This collection of information was previously approved under OMB Control Number 0938–0573, which expired on January 31, 2021. A reinstatement of this PRA package is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

b. Effects of Implementation of Proposal To Adopt Revised OMB Labor Market Area Delineations on Reclassified Hospitals

(1) Background

Reclassifications granted under section 1886(d)(10) of the Act are effective for 3 fiscal years, so that a hospital or county group of hospitals would be assigned a wage index based upon the wage data of hospitals in the labor market area to which it reclassified for a 3-year period. Because hospitals that have been reclassified beginning in FY 2023, 2024, or 2025 were reclassified based on the current labor market delineations, if we adopt the revised OMB delineations based on the OMB Bulletin No. 23–01 beginning in FY 2025 the CBSAs to which they have been reclassified, or the CBSAs where they are located, may change. Hospitals with current reclassifications are encouraged to verify area wage indexes in Table 2 in the appendix of the proposed rule, and to confirm that the CBSAs to which they have been reclassified for FY 2025 would continue to provide a higher wage index than their geographic area wage index. Hospitals may withdraw or terminate their FY 2025 reclassifications by contacting the MGCRB within 45 days from the date this proposed rule is issued in the **Federal Register** (§ 412.273(c)).[138]

(2) Proposed Assignment Policy for Hospitals Reclassified to a CBSA Where One or More Counties Move to the Rural Area or One or More Rural Counties Move Into the CBSA

In the case where a CBSA would add a current rural county, or lose a current constituent rural county, the current reclassification to the resulting proposed CBSA would be maintained. In some cases, a hospital may be located in a rural county that is proposed to join the CBSA to which the hospital is reclassified. We note that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49977), CMS terminated reclassifications when, as a result of adopting the revised OMB delineations, a hospital's geographic county was located in the CBSA for which it was approved for MGCRB reclassification. At that time, there was no means for a hospital to obtain an MGCRB reclassification to its own geographic area (which we refer to as ''home area'' reclassifications). However, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56925), ''home area'' reclassifications have since become possible as a result of the change in policy in the 2016 IFC (81 FR 23428 through 23438) discussed earlier allowing for dual reclassifications. We therefore do not believe it is necessary to terminate these reclassifications as we did in FY 2015. In general, once the MGCRB has approved a reclassification in accordance with subpart L of 42 CFR part 412, that reclassification remains in place for 3 years (see § 412.274(b)(2)) unless terminated by the hospital pursuant to § 412.273, and CMS does not reevaluate whether the hospital continues to meet the criteria for reclassification during the three-year period. As such, we propose to maintain these as ''home area'' reclassifications instead of terminating them.

If a county is proposed to be removed from a CBSA and becomes rural, a hospital in that county with a current ''home area'' reclassification would no longer be geographically located in the CBSA to which they are reclassified. We propose that these reclassifications would no longer be considered ''home area'' reclassifications, and the hospital would be assigned the wage index applicable to other hospitals that reclassify into the CBSA (which may be lower than the wage index calculated for hospitals geographically located in the CBSA due to the hold harmless provision at section 1886(d)(8)(C)(i) of the Act).[139]

Finally, as discussed in section III.B.4, all the constituent counties of CBSA 14100 (Bloomsberg-Berwick, PA), CBSA 19180 (Danville, IL), CBSA 20700 (East Stroudsburg, PA) and CBSA 35100 (New Bern, NC) become rural if we adopt the revised OMB delineations. There are currently 6 hospitals with reclassifications to these areas.

MGCRB Case No.	CCN	Reclassification CBSA
23C0258	140113	19180
24C0548	340142	35100
25C0039	390013	14100
25C0491	390137	20700
25C0492	390237	20700
24C0541	390045	14100

As there is no sufficiently similar CBSA in the proposed delineations, we are proposing that hospital reclassifications to these CBSAs would be terminated for FY 2025. While we prefer to maintain the remaining years of a MGCRB reclassification and transition the reclassified hospitals to the most appropriate proposed CBSA, in an instance when there is no urban county remaining, there is no equivalent urban area that can be assigned to the reclassified hospital. We note that Case No. 24C0548 is a ''home area'' reclassification, and the termination would have no direct effect on wage index calculations.

(3) Proposed Assignment Policy for Hospitals Reclassified to a CBSA Where the CBSA Number Changes, or the CBSA Is Subsumed by Another CBSA

We propose that in the case of a CBSA that experiences a change in CBSA number, or where all urban counties in the CBSA are subsumed by another CBSA, MGCRB reclassifications approved to the FY 2024 CBSA would be assigned the proposed revised FY 2025 CBSA (as described in the section III.B.6). In some cases, this reconfiguration of CBSAs would result in an MGCRB reclassification approved to a different area becoming a ''home area'' reclassification, if a hospital's current geographic urban CBSA is subsumed by its reclassified CBSA. Otherwise, the current reclassification would continue to the proposed revised CBSA number.

(4) Proposed Assignment Policy for Hospitals Reclassified to CBSAs Where One or More Counties Move to a New or Different Urban CBSA

In some cases, adopting the revised OMB delineations would result in one or more counties splitting apart from their current CBSAs to form new CBSAs, or counties shifting from one CBSA designation to another CBSA. If CBSAs are split apart, or if counties shift from one CBSA to another under the revised OMB delineations, for hospitals that have reclassified to these CBSAs we must determine which reclassified area to assign to the hospital for the remainder of a hospital's 3-year reclassification period.

Consistent with the policy implemented in FY 2021 (85 FR 58743 through 58753), we are proposing to assign current ''home area'' reclassifications to these CBSAs to the hospital's proposed geographic CBSA. That is, hospitals that were approved for MGCRB reclassification to the geographic area they are located in effective for FYs 2023, 2024, or 2025 would continue to be assigned a reclassification to their geographic ''home area.'' The assigned ''home area''

[139] In accordance with section 1886(d)(8)(C)(i) of the Act, the wage index for hospitals located in a geographic area cannot be reduced by the inclusion of reclassified hospitals. Therefore, hospitals reclassified into the area would receive a wage index that includes their data, whereas hospitals geographically located there would receive a wage index that does not.

reclassification CBSA may be different from previous years if the hospital is located in a county that was relocated to a new or different urban CBSA.

The following is a table of hospitals with current active ''home area'' reclassification to CBSAs where one or more counties are proposed to move to a new or different urban CBSA. The table also lists reclassifications (noted by an asterisk on the ''MGCRB Case Number'') that were approved in FY 2023 or FY 2024 and would be superseded by a new FY 2025 reclassification. Per § 412.273(d)(4), these prior year reclassifications are terminated once a new reclassification becomes effective. However, if the new reclassification is withdrawn, the prior year reclassification (often referred to as a ''fallback'' reclassification) would become active.

ASSIGNED HOME AREA RECLASSIFICATIONS			
CCN	MGCRB CASE NUMBER	Approved CBSA	Proposed FY 25 CBSA
100067	25C0461	45300	41304
100075	25C0462	45300	45294
100127	25C0463	45300	41304
100128	25C0439	45300	45294
100248	25C0431	45300	41304
100265	25C0465	45300	41304
150035	24C0222*	23844	29414
190036	25C0118	35380	35380
360048	24C0411*	45780	45780
360075	25C0526	17460	17410
360077	25C0527	17460	17410
360123	25C0525	17460	17410
360137	24C0418	17460	17410
360180	24C0023	17460	17410
360230	25C0528	17460	17410
420085	25C0464	34820	34820
490113	25C0250	47894	11694
500005	24C0300	42644	42644
520021	25C0238	29404	28450

Consistent with the policy CMS implemented in the FY 2005 IPPS final rule (69 FR 49054 through 49056), the FY 2015 IPPS final rule (79 FR 49973 through 49977), and in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58753), for FY 2025, if a CBSA would be reconfigured due to adoption of the revised OMB delineations and it would not be possible for the reclassification to continue seamlessly to the reconfigured CBSA (not including ''home area'' reclassifications, which were discussed previously), we believe it would be appropriate for us to determine the best alternative location to assign current reclassifications for the remaining 3 years. Therefore, to maintain the integrity of a hospital's 3-year reclassification period, we are proposing that current geographic reclassifications (applications approved effective for FY 2023, FY 2024, or FY 2025) that would be affected by CBSAs that are split apart or counties that shift to another CBSA under the revised OMB delineations, would ultimately be assigned to a CBSA under the revised OMB delineations that contains at least one county (or county equivalent) from the reclassified CBSA under the current FY 2024 delineations, and that would be generally consistent with rules that govern geographic reclassification. That is, consistent with the policy finalized in FY 2015 (79 FR 49973) we are proposing a policy that other affected reclassified hospitals be assigned to a CBSA that would contain the most proximate county that (1) is located outside of the hospital's proposed FY 2025 geographic labor market area, and (2) is part of the original FY 2024 CBSA to which the hospital is reclassified. We believe that assigning reclassifications to the CBSA that contains the nearest county that meets the aforementioned criteria satisfies the statutory requirement at section 1886(d)(10)(v) of the Act by maintaining reclassification status for a period of 3 fiscal years, while generally respecting the longstanding principle of geographic proximity in the labor market reclassification process. For county group reclassifications, we would follow our proposed policy, as previously discussed, except that we are proposing to reassign hospitals in a county group reclassification to the CBSA under the revised OMB delineations that contains the county to which the majority of hospitals in the group reclassification are geographically closest. We are also proposing to allow such hospitals, or county groups of hospitals, to submit a

request to the *wageindex@cms.hhs.gov* mailbox for reassignment to another proposed CBSA that would contain a county that is part of the current CBSA to which it was approved to be reclassified (based on FY 2024 delineations) if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules, as described later in this section.

The following Table X provides a list of current FY 2024 CBSAs (column 1) where one or more counties would be relocated to a new or different urban CBSA. Hospitals with active MGCRB reclassifications into the current FY 2024 CBSAs in column 1 would be subject to the proposed reclassification assignment policy described in this subsection. The third column of ''eligible'' CBSAs lists all proposed revised CBSAs that contain at least one county that is part of the current FY 2024 CBSA (in column 1).

Table X. CBSAs Where One or More Counties Would be Relocated to a New or Different Urban CBSA.

Approved CBSA	Approved CBSA Name	Eligible CBSA
42644	Seattle-Bellevue-Kent, WA	42644, 21794
12060	Atlanta-Sandy Springs-Alpharetta, GA	12054, 31924
29404	Lake County-Kenosha County, IL-WI	29404, 28450
45300	Tampa-St. Petersburg-Clearwater, FL	45294, 41304
44140	Springfield, MA	44140, 11200
35380	New Orleans-Metairie, LA	35380, 43640
45780	Toledo, OH	45780, 41780
21060	Elizabethtown-Fort Knox, KY	21060, 31140
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764, 11694, 30500
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	34820, 48900
34100	Morristown, TN	34100, 28940

Table Y lists all hospitals subject to our proposed reclassification assignment policy and where their reclassifications would be assigned for FY 2025 under this proposed policy. The table lists reclassifications that would be in effect for FY 2025 under our proposed policy and that are included in Table 2 in the addendum of this proposed rule. The table also includes reclassifications (noted by an asterisk on the ''MGCRB Case Number'') that were approved in FY 2023 or FY 2024 and that would be superseded by a new FY 2025 reclassification. As discussed previously, these prior year ''fallback'' reclassifications would become active if the subsequent FY 2025 reclassification is withdrawn. Please note, the following table does not include hospitals currently reclassified to their ''home'' geographic area, which are discussed previously in this section.

Table Y. Hospitals Subject to Proposed Reclassification Assignment Policy			
CCN	**MGCRB Case No.**	**Current Approved CBSA**	**Proposed Assigned CBSA**
010022	25C0310	12060	31924
070028	25C0375	39100	28880
100023	23C0489	45300	45294
100052	25C0460	45300	45294
100157	24C0076*	45300	45294
100249	24C0220*	45300	45294
110001	24C0022	12060	12054
110002	24C0020	12060	12054
110006	25G0135	12060	12054
110016	24C0063	12060	12054
110023	23C0154	12060	31924
110029	23C0022	12060	12054
110054	25C0307	12060	12054
110064	25C0003	12060	12054
110074	25G0135	12060	12054
110107	24C0149	12060	12054
110150	24C0146	12060	12054
110168	23C0052	12060	31924
110189	23C0240	12060	12054
140008	25C0131	23844	29414
140054	25C0132	23844	29414
140065	25C0282	23844	29414
140088	25C0260	23844	29414
140117	25C0293	23844	29414
140119	25C0302	23844	29414
140150	25C0229	23844	29414
140179	25C0332	23844	29414
140180	25C0292	23844	29414
140276	25C0133	23844	29414
140281	25C0599	23844	29414
150076	25C0143	23844	29414
190004	23C0517	35380	35380
190183	25C0243	35380	35380
250019	25C0606	35380	43640
250162	25C0244	35380	43640
310044	24C0521*	35154	29484
330224	23C0097*	39100	28880
340068	24C0202*	34820	34820
360020	24C0362	17460	17410
360025	25C0342	17460	17410
360027	24C0002	17460	17410
360055	25C0080	17460	17410
360064	24C0123*	17460	17410

Table Y. Hospitals Subject to Proposed Reclassification Assignment Policy			
CCN	MGCRB Case No.	Current Approved CBSA	Proposed Assigned CBSA
360065	25C0120	17460	17410
360070	23C0167	17460	17410
360078	24G0414	17460	17410
360084	24C0057	17460	17410
360095	23C0472*	45780	45780
390138	25C0547	47894	47764
390204	25C0134	35154	29484
390211	25C0081	17460	17410
390258	24C0384*	35154	29484
400123	23C0137	41900	32420
420051	23C0470	34820	34820
420091	24C0454	34820	34820
420098	24C0065	34820	34820
490004	25C0275	47894	11694
490005	23C0081	47894	11694
490009	25C0469	47894	11694
490059	24C0125	47894	11694
490069	24C0126	47894	11694
490077	24C0130*	47894	11694
490112	25C0114	47894	11694
500003	23G0158	42644	21794
500007	23G0158	42644	21794
500016	23C0049	42644	42644
500024	24C0428*	42644	42644
510008	25C0141	47894	11694
520051	25C0284	29404	28450
520096	25C0285	29404	28450

(5) Proposed Assignment Policy for Hospitals Reclassified to CBSAs Reconfigured Due to the Migration to Connecticut Planning Regions

As discussed in section III.B., CMS is proposing to adopt the revised OMB Bulletin No. 23–01 delineations, which use planning regions instead of counties as the basis for CBSA construction in the State of Connecticut. There are five current urban CBSAs that include at least one county in Connecticut. These are 14860 (Bridgeport-Stamford-Norwalk, CT), 25540 (Hartford-East Hartford-Middletown, CT), 35300 (New Have-Milford, CT), 35980 (Norwich-New London, CT), and 49340 (Worcester, MA-CT). In the proposed FY 2025 CBSAs, based on the OMB Bulletin No. 23–01 delineations, there are five CBSAs that will contain at least one county-equivalent ''planning region.'' The five CBSAs are 14860 (Bridgeport-Stamford-Danbury, CT), 25540 (Hartford-West Hartford-East Hartford, CT), 35300 (New Haven, CT), 35980 (Norwich-New London-Willimantic, CT), and 47930 (Waterbury-Shelton, CT).

As there was significant reconfiguration of the CBSAs due to the transition from counties to planning regions, we are proposing to adopt a similar assignment policy for hospitals reclassified to CBSAs that currently include Connecticut counties as we do for hospitals reclassified to CBSAs where one or more counties move to a new or different urban CBSA (described in the previous subsection).

The following table lists all current ''home area'' reclassifications to one of the CBSAs that currently contain at least one county in Connecticut.

ASSIGNED HOME AREA RECLASSIFICATIONS			
CCN	Case Number	Approved CBSA	Proposed FY 25 CBSA
070010	23C0420	14860	14860
070018	23C0422*	14860	14860
070028	23C0454*	14860	14860
070006	23C0455*	14860	14860
07B022	24C0497	14860	14860
070025	24C0499*	25540	25540
070024	24C0500	35980	35980
070031	25C0373	35300	47930
070034	25C0394	14860	14860
070033	25C0396	14860	14860

The following table provides a list of current FY 2024 CBSAs (column 1) that contain at least one county in Connecticut. Hospitals with active MGCRB reclassifications into the CBSAs in column 1 would be subject to the proposed reclassification assignment policy. The third column of ''eligible'' CBSAs lists all proposed revised CBSAs that contain at least one planning region that is part of the current FY 2025 CBSA (in column 1). Consistent with the policy proposed in the previous section, we are proposing a policy that affected reclassified hospitals be assigned to a CBSA that would contain the most proximate planning region that (1) is located outside of the hospital's proposed FY 2025 geographic labor market area, and (2) contains a portion of a county included in the original FY 2024 CBSA to which the hospital is reclassified.

Table X. CBSAs Where One or More County Equivalents Would be Relocated to a New or Different Urban CBSA		
Approved CBSA	**Approved CBSA Name**	**Eligible CBSA**
14860	Bridgeport-Stamford-Norwalk, CT	14860, 47930
25540	Hartford-East Hartford-Middletown, CT	25540, 47930
35300	New Haven-Milford, CT	35300, 47930
35980	Norwich-New London, CT	35980, 25540
49340	Worcester, MA-CT	49340, 35980

The following table lists all hospitals subject to our proposed reclassification assignment policy and their reclassifications to a CBSA reconfigured due to the adoption of Connecticut planning regions in FY 2025 under this proposed policy. The table lists reclassifications that would be in effect for FY 2025 under our proposed policy, and that are included in Table 2 in the addendum of this proposed rule. The table also includes reclassifications (noted by an asterisk on the ''MGCRB Case Number'') that were approved in FY 2023 or FY 2024 and would be superseded by a new FY 2025 reclassification. These prior year reclassifications, frequently referred to as ''fallback'' reclassifications, may become active if the subsequent FY 2025 reclassification is withdrawn. (Please note, the following table does not include hospitals currently reclassified to their ''home'' geographic area, which are discussed previously in this section.)

Hospitals Subject to Proposed Reclassification Assignment Policy			
CCN	MGCRB Case	Current Approved CBSA	Proposed Assigned CBSA
070002	23C0378	35300	47930
070017	25C0376	14860	47930
070020	25C0245	14860	47930
070022	25C0421	14860	47930
070025	25C0377	35300	47930
070031	23C0418*	14860	14860
070035	25C0379	14860	47930
070036	24C0522*	35300	47930
070036	25C0399	35980	35980
07B010	25C0412	14860	14860
220020	23C0205	49340	49340
220077	24C0318	49340	49340
330023	25C0391	14860	14860
330046	23C0433*	14860	14860
330059	23C0444*	14860	14860
330119	23C0439*	14860	14860
330169	23C0432*	14860	14860
330195	23C0440*	14860	14860
330202	23C0431*	14860	14860
330214	23C0435*	14860	14860
330270	23C0434*	14860	14860
33B195	23C0441*	14860	14860
33B234	25C0062	14860	14860
410009	25G0087	49340	35980

We note that the remote location currently indicated with 07B033 would, as proposed, be located in the same CBSA as the main provider 070033. Therefore, it would no longer be necessary to identify this remote location separately from the main provider for wage index purposes, and its MGCRB reclassification would no longer be listed in Table 2 of the addendum of this proposed rule.

We believe that assigning reclassifications to the CBSA that contains the nearest county-equivalent planning region that meets the aforementioned criteria satisfies the statutory requirement at section 1886(d)(10)(v) of the Act by maintaining reclassification status for a period of 3 fiscal years, while generally respecting the longstanding principle of geographic proximity in the labor market reclassification process. For county group reclassifications, we would follow our proposed policy, as previously discussed, except that we are proposing to reassign hospitals in a county group reclassification to the CBSA under the revised OMB delineations that contains the county-equivalent to which the majority of hospitals in the group reclassification are geographically closest. We are also proposing to allow such hospitals, or county groups of hospitals, to submit a request to the *wageindex@cms.hhs.gov* mailbox for reassignment to another proposed CBSA that would contain a county that is part of the current CBSA to which it was approved to be reclassified (based on FY 2024 delineations) if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules.

(6) Instructions To Request Reassignment of Reclassified CBSA

Hospitals that wish to be reassigned to an eligible CBSA (other than the CBSA to which their reclassification would be assigned in this proposed rule) for which they meet the applicable proximity criteria under subpart L of 42 CFR part 412 may request reassignment within 45 days from the date the proposed rule is placed on display at the **Federal Register**. Hospitals must send a request to *wageindex@cms.hhs.gov* and provide documentation establishing that they meet the requisite proximity criteria for reassignment to an alternate CBSA that contains one or more counties (or county-equivalents) from the CBSA to which they are currently reclassified. We believe this option of allowing hospitals to submit a request to CMS would provide hospitals with greater flexibility with respect to their reclassification reassignment, while ensuring that the proximity requirements are met. We believe that where the proximity requirements are met, the reclassified wage index would be consistent with the labor market area to which the hospitals were originally approved for reclassification. A hospital may request to reassign an individual reclassification to any CBSA that in FY 2025 would contain a county or county-equivalent (or in the case of Connecticut CBSAs, a portion of a county) from the CBSA to which it was approved to be reclassified (based on FY 2024 delineations). However, to be reassigned to an area that is not the most proximate to the hospital, we believe it is necessary that the hospital demonstrates that it complies with the applicable proximity criteria under subpart L of 42 CFR part 412. If a hospital cannot demonstrate proximity to a different eligible CBSA, the hospital would not be considered for reclassification to that labor market area, and the reclassification would remain with the CBSA assigned under the general policy proposed earlier in this section. In the case of a county group reclassification, all requests for reassignment must include all actively reclassified hospitals (that is, excluding any hospital that has since closed or converted to a different provider type, or has terminated the reclassification). County

groups must also demonstrate that they meet the appropriate proximity requirements, including, for rural county groups, being adjacent to the MSA to which they seek redesignation (412.232(a)(1)(ii)), and for urban county groups, being in the same Combined Statistical Area or CBSA as the urban area to which they seek redesignation (412.234(a)(3)(iv)).

All hospital requests for reassignment should contain the hospital's name, address, CCN, and point of contact information. All requests must be sent to *wageindex@cms.hhs.gov.* Changes to a hospital's CBSA assignment on the basis of a hospital's disagreement with our determination of closest county, or on the basis of being granted a reassignment due to meeting applicable proximity criteria under subpart L of 42 CFR part 412 to an eligible CBSA will be announced in the FY 2025 IPPS/LTCH PPS final rule. In any cases where a hospital requested the Administrator review a reclassification dismissal or denial by the MGCRB, the assignment and reassignment policies discussed in this proposed rule would apply if the Board's decision is overturned; that is, if the Administrator decides that the hospital's reclassification request should be granted but the CBSA to which the hospital would reclassify based on that decision would potentially be assigned to a different CBSA as a result of adoption of the new OMB delineations, the policies discussed in this proposed rule would apply to that assignment. At the time of writing, CMS does not have a list of cases for which the Administrator's review has been requested, nor the disposition of any such cases. If a hospital is requesting review of a reclassification to one of the CBSAs discussed in this section, they may contact *wageindex@cms.hhs.gov* to confirm to what CBSA the reclassification would be assigned.

We recognize that the proposed reclassification assignment policies may result in the assignment of the hospital for the remainder of its 3-year reclassification period to a CBSA that has a lower wage index than the wage index that would have been assigned for the reclassified hospital in the absence of the proposed adoption of the revised OMB delineations. We believe that the 5 percent cap on negative wage index changes discussed in section III.G.6 would mitigate significant negative payment impacts for FY 2025, and hospitals would have adequate time to fully assess any additional reclassification options available to them.

d. Proposed Change to Timing of Withdrawals at 412.273(c)

As mentioned in section III.F.3.a of this proposed rule, under the regulations at § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw or terminate an approved reclassification. The current regulations at § 412.273(c)(1)(ii) and (c)(2) for withdrawals and terminations require the request to be received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the IPPS and proposed payment rates.

In the 2018 IPPS/LTCH PPS Final Rule (82 FR 38148 through 38150), we finalized changes to the 45-day notification rules so that hospitals have 45 days from the public display of the annual proposed rule for the IPPS instead of 45 days from publication to inform CMS of certain requested changes relating to the development of the hospital wage index. We stated that we believe that the public has access to the necessary information from the date of public display of the proposed rule at the Office of the Federal Register and on its website in order to make the decisions at issue. While we finalized changes to the 45-day notification rules for decisions about the outmigration adjustment and waiving Lugar status, we did not finalize a change to the timing for withdrawing or terminating MGCRB decisions.

Instead, in response to comments expressing concern that some hospitals may be disadvantaged if the Administrator's decision on a hospital's request for review of an MGCRB decision has not been issued prior to the proposed deadline for submitting withdrawal or termination requests to the MGCRB, we maintained our existing policy of requiring hospitals to request from the MGCRB withdrawal or termination of an MGCRB reclassification within 45 days of issuance in the **Federal Register**. We stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38149) that considering the usual dates of the MGCRB's decisions (generally early February) and of the public display of the IPPS proposed rule, the maximum amount of time for an Administrator's decision to be issued may potentially extend beyond the proposed deadline of 45 days from the date of public display.

However, the MGCRB currently issues decisions earlier, in January, which mitigates this concern. For example, the MGCRB has sent decision letters to hospitals via email on January 23, 2024 for the FY 2025 cycle and on January 31, 2023 for the FY 2024 cycle. We believe that the MGCRB will continue to issue its decisions in January, due to their upgrade to an electronic system that expedites processing applications and issuing decision letters efficiently. The regulations at §§ 412.278(a) and (b)(1) provide that a hospital may request the Administrator to review the MGCRB decision within 15 days after the date the MGCRB issues its decision. Under § 412.278(f)(2)(i), the Administrator issues a decision not later than 90 days following receipt of the party's request for review. Consequently, MGCRB decisions could be issued as late as the end of January, and the 15 days the hospital has to request the Administrator's review, plus the 90 days the Administrator has to issue a decision, would result in hospitals receiving the results of the review prior to 45 days after display (which would be May 16th if the proposed rule is displayed on the target date of April 1, but later if there is a delay).

While the current timing of MGCRB decisions in January allows for hospitals to receive the results of any review prior to 45 days after display of the proposed rule for the relevant FY, and we expect this timing to continue, we acknowledge that section 1886(d)(10)(C)(iii)(I) of the Act grants the MGCRB 180 days after the application deadline to render a decision. If the MGCRB were to delay issuing decisions until the last day possible according to the Statute, which is February 28th, a hospital requesting the Administrator's review may not receive the results of the review prior to 45 days after display.

Therefore, we are proposing to change the deadline for hospitals to withdraw or terminate MGCRB classifications from within 45 days of the date that the annual notice of proposed rulemaking is issued in the **Federal Register** to within 45 days of the public display of the annual notice of proposed rulemaking on the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator in accordance with § 412.278 of this part, whichever is later. This proposed change will synchronize this deadline with other wage index deadlines, such as the deadlines for accepting the outmigration adjustment and waiving or reinstating Lugar status. As hospitals typically know the results of the Administrator's decisions on reviews within 45 days of the public display of the proposed rule for the upcoming fiscal year, we believe hospitals have access to the information they need to make reclassification decisions. In the rare circumstance that a hospital would not receive the results

of the review prior to 45 days of the public display date, or receives the results of the review less than 7 days before the deadline, the hospital would have 7 calendar days after receiving the Administrator's decision to request to withdraw or terminate MGCRB classification. While we do not anticipate frequent use of this extension, we believe this fully addresses the concern that some hospitals may be disadvantaged if the Administrator's decision on a hospital's request for review of an MGCRB decision has not been issued prior to the proposed deadline for submitting withdrawal or termination requests to the MGCRB. We believe that 7 days after receiving the Administrator's decision affords hospitals adequate time to make calculated reclassification decisions.

Specifically, we are proposing to change the words ''within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register**'' in the regulation text at 412.273(c)(1)(ii) and 412.273(c)(2) for withdrawals and terminations to ''within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator in accordance with § 412.278 of this part, whichever is later''.

4. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the issuance of the proposed rule in the **Federal Register**) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of the issuance of the proposed rule in the **Federal Register** for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov.* In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov.* To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an outmigration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

b. Effects of Proposed Implementation of Revised OMB Labor Market Area Delineations on Redesignations Under Section 1886(d)(8)(B) of the Act

As discussed in section III.A.2. of the preamble of this proposed rule, CMS is proposing to update the CBSA labor market delineations to reflect the changes made in the July 15, 2023, OMB Bulletin 23–01. In that section, we proposed that 54 currently rural counties be added to new or existing urban CBSAs. Of those 54 counties, 22 are currently deemed urban under section 1886(d)(8)(B) of the Act. Hospitals located in such a ''Lugar'' county, barring another form of wage index reclassification, are assigned the reclassified wage index of a designated urban CBSA. Section 1886(d)(8)(B) of the Act defines a deemed urban county as a ''rural county adjacent to one or more urban areas'' that meets certain commuting thresholds. Since we are proposing to modify the status of these 22 counties from rural to urban, they would no longer qualify as ''Lugar'' counties. Hospitals located within these counties would be considered geographically urban under the revised OMB delineations. The table in this section of this rule lists the counties that would no longer be deemed urban under section 1886(d)(8)(B) of the Act if we adopt the revised OMB delineations. We note that in almost all instances, the ''Lugar'' county is joining the same (or a substantially similar) urban CBSA as it was deemed to in FY 2024.

COUNTIES THAT WOULD NO LONGER BE DEEMED URBAN UNDER 1886(d)(8)(B) OF THE ACT DUE TO PROPOSED URBAN GEOGRAPHICAL STATUS			
FIPS County Code	**County Name**	**Proposed FY 25 CBSA**	**Proposed FY 25 CBSA Name**
01087	MACON	12220	Auburn-Opelika, AL
01127	WALKER	13820	Birmingham, AL
12133	WASHINGTON	37460	Panama City-Panama City Beach, FL
13187	LUMPKIN	12054	Atlanta-Sandy Springs-Roswell, GA
15005	KALAWAO	27980	Kahului-Wailuku, HI
17053	FORD	16580	Champaign-Urbana, IL
18159	TIPTON	26900	Indianapolis-Carmel-Greenwood, IN
18179	WELLS	23060	Fort Wayne, IN
21179	NELSON	31140	Louisville/Jefferson County, KY-IN
22053	JEFFRSON DAVIS	29340	Lake Charles, LA
26015	BARRY	24340	Grand Rapids-Wyoming-Kentwood, MI
28009	BENTON	32820	Memphis, TN-MS-AR
32019	LYON	39900	Reno, NV
39007	ASHTABULA	17410	Cleveland, OH
42073	LAWRENCE	38300	Pittsburgh, PA
45087	UNION	43900	Spartanburg, SC
46033	CUSTER	39660	Rapid City, SD
47081	HICKMAN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	18580	Corpus Christi, TX
48035	BOSQUE	47380	Waco, TX
51063	FLOYD	13980	Blacksburg-Christiansburg-Radford, VA
51181	SURRY	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC

We note that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49973 through 49977), when we adopted large scale changes to the CBSA labor market delineations based on the new 2010 decennial census, we also re-evaluated the commuting data thresholds for all eligible rural counties in accordance with the requirement set forth in section 1886(d)(8)(B)(ii)(II) of the Act to base the list of qualifying hospitals on the most recently available decennial population data. We are therefore proposing to reevaluate the ''Lugar'' status for all counties in FY 2025 using the same commuting data table used to develop the OMB Bulletin No. 23–01 revised delineations. The data table is the ''2016–2020 5-Year American Community Survey Commuting Flows'' (available on OMB's website: *https://www.census.gov/data/tables/2020/demo/metro-micro/commuting-flows-2020.html*). We are also proposing to use the same methodology discussed in the FY 2020 IPPS/LTCH final rule (84 FR 42315 through 42318) to assign the appropriate reclassified CBSA for hospitals in ''Lugar'' counties. That is, when assessing which CBSA to assign, we will sum the total number of workers that commute from the ''Lugar'' county to both ''central'' and ''outlying'' urban counties (rather than just ''central'' county commuters).

By applying the 2020 American Community Survey (ACS) commuting data to the updated OMB labor market delineations, we are proposing the following changes to the current ''Lugar'' county list: 17 of the 53 urban counties that are proposed to become rural under the revised OMB delineations, and both newly created rural Connecticut planning region county-equivalents would qualify as ''Lugar'' counties. We also have determined that, as proposed, 33 rural counties (an approximately 11 hospitals) would lose ''Lugar'' status, as the county no longer meets the commuting thresholds or adjacency criteria specified in section 1886(d)(8)(B) of the Act.

COUNTIES THAT WOULD NO LONGER BE DEEMED URBAN UNDER 1886(d)(8)(B) OF THE ACT DUE TO NOT MEETING CRITERIA (based on proposed revised OMB delineations and 2020 census data)			
FIPSCD	County	FY 2024 "Lugar" CBSA	FY 2024 "Lugar" CBSA Name
01017	CHAMBERS	12220	Auburn-Opelika, AL
02068	DENALI	21820	Fairbanks, AK
12045	GULF	37460	Panama City, FL
13007	BAKER	10500	Albany, GA
13235	PULASKI	47580	Warner Robins, GA
16071	ONEIDA	36260	Ogden-Clearfield, UT
17181	UNION	16060	Carbondale-Marion, IL
18143	SCOTT	31140	Louisville/Jefferson County, KY-IN
19055	DELAWARE	20220	Dubuque, IA
19149	PLYMOUTH	43580	Sioux City, IA-NE-SD
20095	KINGMAN	48620	Wichita, KS
21223	TRIMBLE	31140	Louisville/Jefferson County, KY-IN
22119	WEBSTER	43340	Shreveport-Bossier City, LA
24011	CAROLINE	12580	Baltimore-Columbia-Towson, MD
27131	RICE	33460	Minneapolis-St. Paul-Bloomington, MN-WI
29119	MC DONALD	22220	Fayetteville-Springdale-Rogers, AR
30037	GOLDEN VALLEY	13740	Billings, MT
31081	HAMILTON	24260	Grand Island, NE
36057	MONTGOMERY	10580	Albany-Schenectady-Troy, NY
36105	SULLIVAN	39100	Poughkeepsie-Newburgh-Middletown, NY
38085	SIOUX	13900	Bismarck, ND
40079	LE FLORE	22900	Fort Smith, AR-OK
45029	COLLETON	16700	Charleston-North Charleston, SC
45071	NEWBERRY	17900	Columbia, SC
48031	BLANCO	12420	Austin-Round Rock-Georgetown, TX
48221	HOOD	23104	Fort Worth-Arlington-Grapevine, TX
48425	SOMERVELL	23104	Fort Worth-Arlington-Grapevine, TX
51029	BUCKINGHAM	16820	Charlottesville, VA
53013	COLUMBIA	47460	Walla Walla, WA
53051	PEND OREILLE	44060	Spokane-Spokane Valley, WA
72043	COAMO	41980	San Juan-Bayamón-Caguas, PR
72093	MARICAO	32420	Mayagüez, PR

The following table lists all proposed ''Lugar'' counties for FY 2025. We indicated additions to the list with ''New'' in column 5.

RURAL COUNTIES CONTAINING HOSPITALS THAT WOULD BE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (based on proposed revised OMB delineations and 2020 census data)				
FIPSCD	**County Name**	**Proposed FY 2025 "Lugar" CBSA**	**Proposed FY 2025 "Lugar" CBSA Name**	**Status**
01011	BULLOCK	33860	Montgomery, AL	New
01019	CHEROKEE	40660	Rome, GA	
01029	CLEBURNE	12054	Atlanta-Sandy Springs-Roswell, GA	
01121	TALLADEGA	13820	Birmingham, AL	
01129	WASHINGTON	33660	Mobile, AL	New
05047	FRANKLIN	22900	Fort Smith, AR-OK	New
05059	HOT SPRING	26300	Hot Springs, AR	
09150	NORTHEASTERN CONNECTICUT	35980	Norwich-New London-Willimantic, CT	New
09160	NORTHWEST HILLS	25540	Hartford-West Hartford-East Hartford, CT	New
12007	BRADFORD	27260	Jacksonville, FL	
12107	PUTNAM	27260	Jacksonville, FL	New
12125	UNION	23540	Gainesville, FL	New
13011	BANKS	23580	Gainesville, GA	New
13023	BLECKLEY	47580	Warner Robins, GA	New
13055	CHATTOOGA	16860	Chattanooga, TN-GA	
13157	JACKSON	12054	Atlanta-Sandy Springs-Roswell, GA	
13171	LAMAR	12054	Atlanta-Sandy Springs-Roswell, GA	New
13193	MACON	47580	Warner Robins, GA	New
13233	POLK	31924	Marietta, GA	
16011	BINGHAM	26820	Idaho Falls, ID	New
17021	CHRISTIAN	44100	Springfield, IL	
17039	DE WITT	14010	Bloomington, IL	
17075	IROQUOIS	28100	Kankakee, IL	
17107	LOGAN	44100	Springfield, IL	
17125	MASON	37900	Peoria, IL	
17141	OGLE	40420	Rockford, IL	
18023	CLINTON	29200	Lafayette-West Lafayette, IN	
18055	GREENE	14020	Bloomington, IN	
18065	HENRY	26900	Indianapolis-Carmel-Greenwood, IN	
18099	MARSHALL	43780	South Bend-Mishawaka, IN-MI	

RURAL COUNTIES CONTAINING HOSPITALS THAT WOULD BE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (based on proposed revised OMB delineations and 2020 census data)				
FIPSCD	County Name	Proposed FY 2025 "Lugar" CBSA	Proposed FY 2025 "Lugar" CBSA Name	Status
18133	PUTNAM	26900	Indianapolis-Carmel-Greenwood, IN	New
18147	SPENCER	21780	Evansville, IN	
18149	STARKE	29414	Lake County-Porter County-Jasper County, IN	
19019	BUCHANAN	47940	Waterloo-Cedar Falls, IA	
19031	CEDAR	26980	Iowa City, IA	
19095	IOWA	26980	Iowa City, IA	
20059	FRANKLIN	28140	Kansas City, MO-KS	
21101	HENDERSON	21780	Evansville, IN	New
21213	SIMPSON	34980	Nashville-Davidson--Murfreesboro--Franklin, TN	New
22097	ST. LANDRY	29180	Lafayette, LA	
23017	OXFORD	30340	Lewiston-Auburn, ME	
25011	FRANKLIN	11200	Amherst Town-Northampton, MA	New
26005	ALLEGAN	24340	Grand Rapids-Wyoming-Kentwood, MI	
26091	LENAWEE	11460	Ann Arbor, MI	
26123	NEWAYGO	24340	Grand Rapids-Wyoming-Kentwood, MI	
26155	SHIAWASSEE	29620	Lansing-East Lansing, MI	New
26157	TUSCOLA	40980	Saginaw, MI	
26159	VAN BUREN	28020	Kalamazoo-Portage, MI	
27049	GOODHUE	33460	Minneapolis-St. Paul-Bloomington, MN-WI	
27093	MEEKER	33460	Minneapolis-St. Paul-Bloomington, MN-WI	
27097	MORRISON	41060	St. Cloud, MN	New
27107	NORMAN	22020	Fargo, ND-MN	New
27143	SIBLEY	33460	Minneapolis-St. Paul-Bloomington, MN-WI	
28109	PEARL RIVER	43640	Slidell-Mandeville-Covington, LA	
29057	DADE	44180	Springfield, MO	
31131	OTOE	30700	Lincoln, NE	
32005	DOUGLAS	16180	Carson City, NV	
33013	MERRIMACK	31700	Manchester-Nashua, NH	
35028	LOS ALAMOS	42140	Santa Fe, NM	
36011	CAYUGA	45060	Syracuse, NY	
36021	COLUMBIA	10580	Albany-Schenectady-Troy, NY	
36023	CORTLAND	27060	Ithaca, NY	
36037	GENESEE	40380	Rochester, NY	
36039	GREENE	10580	Albany-Schenectady-Troy, NY	
36049	LEWIS	48060	Watertown-Fort Drum, NY	
36097	SCHUYLER	27060	Ithaca, NY	
36099	SENECA	40380	Rochester, NY	
36121	WYOMING	15380	Buffalo-Cheektowaga, NY	New
37033	CASWELL	15500	Burlington, NC	
37047	COLUMBUS	48900	Wilmington, NC	New
37077	GRANVILLE	39580	Raleigh-Cary, NC	New

RURAL COUNTIES CONTAINING HOSPITALS THAT WOULD BE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (based on proposed revised OMB delineations and 2020 census data)				
FIPSCD	**County Name**	**Proposed FY 2025 "Lugar" CBSA**	**Proposed FY 2025 "Lugar" CBSA Name**	**Status**
37079	GREENE	24780	Greenville, NC	
37085	HARNETT	39580	Raleigh-Cary, NC	New
37149	POLK	43900	Spartanburg, SC	
37195	WILSON	39580	Raleigh-Cary, NC	
38097	TRAILL	24220	Grand Forks, ND-MN	
39021	CHAMPAIGN	18140	Columbus, OH	
39027	CLINTON	17140	Cincinnati, OH-KY-IN	New
39029	COLUMBIANA	49660	Youngstown-Warren, OH	
39067	HARRISON	48260	Weirton-Steubenville, WV-OH	
39077	HURON	41780	Sandusky, OH	New
39135	PREBLE	19430	Dayton-Kettering-Beavercreek, OH	
42035	CLINTON	48700	Williamsport, PA	
42057	FULTON	25180	Hagerstown-Martinsburg, MD-WV	
42059	GREENE	38300	Pittsburgh, PA	
42089	MONROE	10900	Allentown-Bethlehem-Easton, PA-NJ	New
42103	PIKE	35084	Newark, NJ	New
42107	SCHUYLKILL	39740	Reading, PA	
42115	SUSQUEHANNA	42540	Scranton--Wilkes-Barre, PA	
45027	CLARENDON	44940	Sumter, SC	New
45061	LEE	17900	Columbia, SC	
45067	MARION	22500	Florence, SC	
47075	HAYWOOD	27180	Jackson, TN	New
47121	MEIGS	17420	Cleveland, TN	
48147	FANNIN	19124	Dallas-Plano-Irving, TX	
48185	GRIMES	17780	College Station-Bryan, TX	
48213	HENDERSON	19124	Dallas-Plano-Irving, TX	
48217	HILL	47380	Waco, TX	
48283	LA SALLE	29700	Laredo, TX	New
48315	MARION	30980	Longview, TX	New
48331	MILAM	12420	Austin-Round Rock-San Marcos, TX	
48351	NEWTON	13140	Beaumont-Port Arthur, TX	
48391	REFUGIO	18580	Corpus Christi, TX	New
48399	RUNNELS	41660	San Angelo, TX	New
48467	VAN ZANDT	19124	Dallas-Plano-Irving, TX	
48489	WILLACY	15180	Brownsville-Harlingen, TX	
49003	BOX ELDER	36260	Ogden, UT	New
51033	CAROLINE	11694	Arlington-Alexandria-Reston, VA-WV	
51109	LOUISA	16820	Charlottesville, VA	
51137	ORANGE	11694	Arlington-Alexandria-Reston, VA-WV	
51139	PAGE	25500	Harrisonburg, VA	
51171	SHENANDOAH	49020	Winchester, VA-WV	
51620	FRANKLIN CITY	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC	New

RURAL COUNTIES CONTAINING HOSPITALS THAT WOULD BE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (based on proposed revised OMB delineations and 2020 census data)				
FIPSCD	County Name	Proposed FY 2025 "Lugar" CBSA	Proposed FY 2025 "Lugar" CBSA Name	Status
53029	ISLAND	21794	Everett, WA	
53041	LEWIS	36500	Olympia-Lacey-Tumwater, WA	New
53045	MASON	14740	Bremerton-Silverdale-Port Orchard, WA	
53069	WAHKIAKUM	31020	Longview-Kelso, WA	New
54035	JACKSON	16620	Charleston, WV	New
54043	LINCOLN	16620	Charleston, WV	New
54087	ROANE	16620	Charleston, WV	
55047	GREEN LAKE	22540	Fond du Lac, WI	
55055	JEFFERSON	33340	Milwaukee-Waukesha, WI	
55127	WALWORTH	33340	Milwaukee-Waukesha, WI	
72055	GUANICA	38660	Ponce, PR	New
72081	LARES	11640	Arecibo, PR	New
72123	SALINAS	41980	San Juan-Bayamón-Caguas, PR	
72141	UTUADO	11640	Arecibo, PR	New

We note that Litchfield County, CT is no longer listed as a ''Lugar'' county as it is not included in the revised CBSA delineations. The majority of Litchfield County is now within the proposed Northwest Hills Planning Region county-equivalent, with some of the county's current constituent townships assigned to other urban county-equivalents. We also note that in prior fiscal years, Merrimack County, NH was included as a ''Lugar'' redesignated county pursuant to the provision at § 412.62(f)(1)(ii)(B), which deems certain rural counties in the New England region to be part of urban areas. Merrimack County now meets the commuting standards to be considered deemed urban under the ''Lugar'' statute at section 1886(d)(8)(B) of the Act.

We recognize that the changes to the ''Lugar'' list may have negative financial impacts for hospitals that lose deemed urban status. We believe that the 5 percent cap on negative wage index changes discussed in section III.G.6, would mitigate significant negative payment impacts for FY 2025, and would afford hospitals adequate time to fully assess any additional reclassification options available to them. We also note that special statuses limited to hospitals located in rural areas (such as MDH or SCH status) may be terminated if hospitals are deemed urban under section 1886(d)(8)(B) of the Act. In these cases, hospitals should apply for rural reclassification status under § 413.103 prior to October 1, 2024, if they wish to ensure no disruption in status.

G. Wage Index Adjustments: Rural Floor, Imputed Floor, State Frontier Floor, Out-Migration Adjustment, Low Wage Index, and Cap on Wage Index Decrease Policies

The following adjustments to the wage index are listed in the order that they are generally applied. First, the rural floor, imputed floor, and State frontier floor provide a minimum wage index. The rural floor at section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the wage index for hospitals in urban areas of a State may not be less than the wage index applicable to hospitals located in rural areas in that State. The imputed floor at section 1886(d)(3)(E)(iv) of the Act provides a wage index minimum for all-urban states. The state frontier floor at section 1886(d)(3)(E)(iii) of the Act requires that hospitals in frontier states cannot be assigned a wage index of less than 1.0000. Next, the out-migration adjustment at section 1886(d)(13)(A) of the Act is applied, potentially increasing the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county or counties with a higher wage index. The low-wage index hospital adjustment finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339) is then applied, which increases the wage index values for hospitals with wage indexes at or below the 25th percentile. Finally, all hospital wage index decreases are capped at 95 percent of the hospital's final wage index in the prior fiscal year, according to the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

1. Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2025 wage index associated with this proposed rule (which is available via the internet on the CMS website), and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 494 hospitals would receive the rural floor in FY 2025. The budget neutrality impact of the proposed application of the rural floor is discussed in section II.A.4.e. of Addendum A of this proposed rule.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48784), CMS finalized a

policy change to calculate the rural floor in the same manner as we did prior to the FY 2020 IPPS/LTCH PPS final rule, in which the rural wage index sets the rural floor. We stated that for FY 2023 and subsequent years, we would include the wage data of § 412.103 hospitals that have no MGCRB reclassification in the calculation of the rural floor, and include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

In the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy change beginning that year to include the data of *all* § 412.103 hospitals, even those that have an MGCRB reclassification, in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We explained that after revisiting the case law, prior public comments, and the relevant statutory language, we agreed that the best reading of section 1886(d)(8)(E)'s text that CMS ''shall treat the [§ 412.103] hospital as being located in the rural area'' is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation.

Accordingly, in the FY 2024 IPPS/LTCH PPS final rule, we finalized a policy to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) that are implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. (For additional information on these changes, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58971 and 58977).)

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have stated that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at § 412.64(h)(4). For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Section 1886(d)(3)(E)(iv)(IV) of the Act provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178) for further discussion of the original imputed floor calculation methodology implemented in FY 2005 and the alternative methodology implemented in FY 2013.

Based on data available for this proposed rule, States that would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States that would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2025, are identified in Table 3 associated with this proposed rule. States with a value in the column titled ''State Imputed Floor'' would be eligible for the imputed floor.

The regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor would continue to be applied for FY 2025 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

3. State Frontier Floor for FY 2025

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at § 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In this FY 2025 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2025. In this proposed rule, 41 hospitals would receive the frontier floor value of 1.0000 for their FY 2025 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We note that while Nevada meets the criteria of a frontier State, all hospitals within the State are projected to receive a wage index value greater than 1.0000 prior to the application of the frontier floor policy for FY 2025.

The areas affected by the rural and frontier floor policies for the proposed FY 2025 wage index are identified in Table 3 associated with this proposed rule, which is available via the internet on the CMS website.

4. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on

commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time, and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012), we have applied the same policies, procedures, and computations since FY 2012. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source. We also stated that we would consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

As discussed earlier in section III.B., CMS is proposing to adopt revised delineations from the OMB Bulletin 23–01, published July 21, 2023. The revised delineations incorporate population estimates based on the 2020 decennial census, as well as updated journey-to-work commuting data. The Census Bureau once again worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked, for use in developing a new out-migration adjustment based on new commuting patterns. We analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, utilizing 2016 through 2020 data. The Census Bureau produces county level commuting flow tables every 5 years using non-overlapping 5-year ACS estimates. The data include demographic characteristics, home and work locations, and journey-to-work travel flows. The custom tabulation requested by CMS was specific to general medical and surgical hospital and specialty (except psychiatric and substance use disorder treatment) hospital employees (hospital sector Census code 8191/NAICS code 6221 and 6223) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico.

For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.5 million resident addresses per year.[140] The results of the ACS are used to formulate descriptive population estimates, and, as such, the sample on which the dataset is based represents the actual figures that would be obtained from a complete count.

For FY 2025, and subsequent years, we are proposing that the out-migration adjustment will be based on the data derived from the previously discussed custom tabulation of the ACS utilizing 2016 through 2020 (5-year) Microdata. As discussed earlier, we believe that these data are the most appropriate to establish qualifying counties, because they are the most accurate and up-to-date data that are available to us. Furthermore, with the proposed transition of several counties in Connecticut to ''planning region'' county equivalents (discussed in section III.B.3. of the preamble this proposed rule), the continued use of a commuting dataset developed with expiring county definitions would be less accurate in approximating commuting flows. We are proposing that the FY 2025 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2025. (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) Table 2 of this proposed rule (which is available via the internet on the CMS website) lists the proposed out-migration adjustments for the FY 2025 wage index.

5. Proposed Continuation of the Low Wage Index Hospital Policy and Budget Neutrality Adjustment

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to address the artificial magnification of wage index disparities, based in part on comments we received in response to our request for information included in our FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372 through 20377). In the FY 2020 IPPS/LTCH final rule, based on those public comments and the growing disparities between wage index values for high- and low-wage-index hospitals, we explained that those growing disparities are likely caused, at least in part, by the use of historical wage data to prospectively set hospitals' wage indexes. That lag creates barriers to hospitals with low wage index values being able to increase employee compensation, because those hospitals will not receive corresponding increases in their Medicare payment for several years (84 FR 42327). Accordingly, we finalized a policy that provided certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index (as they would expect to do if not for the lag).[141]

[140] According to the Census Bureau, the effects of the PHE on ACS activities in 2020 resulted in a lower number of addresses (~2.9 million) in the sample, as well as fewer interviews than a typical year.

[141] In the FY 2020 IPPS/LTCH proposed rule, we agreed with respondents to a previous request for information who indicated that some current wage index policies create barriers to hospitals with low wage index values from being able to increase

Continued

We accomplished this by temporarily increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. As explained in the FY 2020 IPPS/LTCH proposed rule (84 FR 19396) and final rule (84 FR 42329), we indicated that the Secretary has authority to implement the lowest quartile wage index proposal under both section 1886(d)(3)(E) of the Act and under his exceptions and adjustments authority under section 1886(d)(5)(I) of the Act.

We increased the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that this policy would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation.

We note that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al.,* v. *Becerra,* No. 1:20–cv–01574 (D.D.C.), No. 22–5249 (D.C. Cir.) (hereafter referred to as *Bridgeport*). The district court in *Bridgeport* held that the Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020 and remanded the policy to the agency without vacatur. We have appealed the court's decision.

As noted earlier, we finalized this policy in the FY 2020 IPPS/LTCH final rule to provide low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index (as they would expect to do if not for the lag). This continues to be the purpose of the policy. We stated in the FY 2020 IPPS/LTCH PPS final rule our intention that it would be in effect for at least 4 years beginning October 1, 2019 (84 FR 42326). We also stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. What could not have been anticipated at the time the policy was promulgated was that implementation of the policy would occur during the COVID–19 PHE, which was declared starting in January of 2020 and continued until May of 2023. The effects of the COVID–19 PHE complicate our ability to evaluate the low wage policy and our ability to determine whether low wage hospitals have been provided a sufficient opportunity to increase employee compensation under the policy without the usual lag.

In order to help gauge the impact of the COVID–19 PHE relative to the impact of the low wage index hospital policy, we examined the aggregate revenue each hospital reported on their FY 2020 cost reports from the COVID–19 PHE Provider Relief Fund, the Small Business Association Loan Forgiveness program, and other sources of COVID–19 related funding such as payroll retention credits and State emergency relief funds. Specifically, we examined Worksheet G–3, lines 24.50 through 24.60 for each IPPS hospital's 2020 cost report. We found that hospitals in the aggregate reported $31.1 billion in COVID–19 related funding, and of that amount low wage hospitals reported $3.6 billion. These amounts are much larger than, and likely had a much greater impact on hospital operations, the approximately $230 million impact of the low wage index hospital policy.[142] For example, COVID–19 related funding impacted the ability of hospitals, both low wage hospitals and non-low wage hospitals, to change employee compensation in ways that overshadowed any differential impact of the low wage index hospital policy between the two groups that may have occurred in the absence of the COVID–19 PHE.

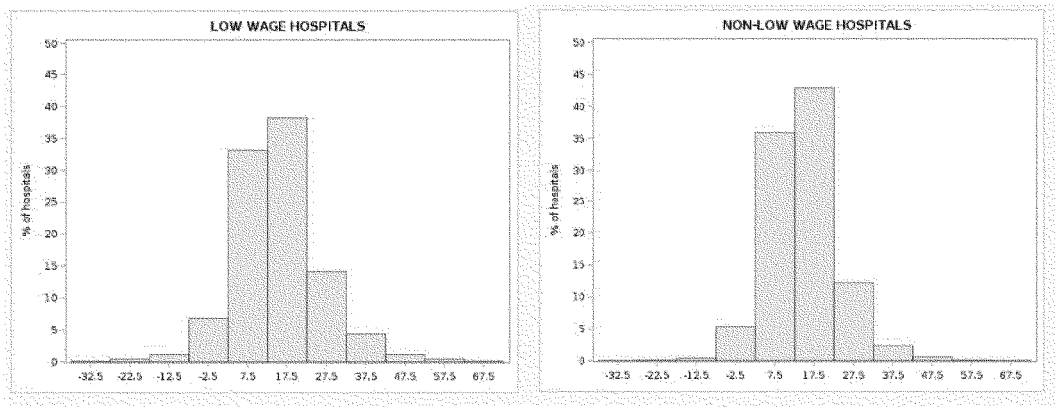
In addition to examining the COVID–19 related funding data, we also examined the wage index data itself. For the FY 2025 wage index the best available data typically would be from the FY 2021 wage data from hospital cost reports. As discussed earlier in more detail in section III.C, in considering the impacts of the COVID–19 PHE on the FY 2021 hospital wage data, we compared that data with recent historical data. While there are some differences, it is not readily apparent how any changes due to the COVID–19 PHE *differentially* impacted the wages paid by individual hospitals. Furthermore, even if changes due to the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data to account for the effects of the COVID–19 PHE. Our inability to isolate the wage data changes due to the COVID–19 PHE and disentangle them from changes due to the low wage index hospital policy makes isolating and evaluating the impact of the low wage index hospital policy challenging. We reached similar conclusions with respect to the FY 2020 hospital wage data.

To help further inform our FY 2025 rulemaking with respect to the low wage index hospital policy, we also conducted an analysis of hospitals that received an increase to their wage index due to the policy in FY 2020 (referred to as the low wage index hospitals for brevity in the following discussion). Specifically, for each low wage index hospital we calculated the percent increase in its average hourly wages (AHWs) from FY 2019 to FY 2021 based on dividing its FY 2021 average hourly wage (using the wage data one year after the low wage index hospital policy was implemented in FY 2020, available on the FY 2025 IPPS Proposed Rule web page) by its average hourly wage from the FY 2019 wage data (the wage data one year before the low wage index hospital policy was implemented in FY 2020, available on the FY 2023 IPPS final rule web page). We performed the same calculation for the hospitals that were not low wage index hospitals. We then compared the distributions of the average hourly wage increases between the two groups. The results are shown in the following chart (Chart 1).

employee compensation due to the lag between when hospitals increase the compensation and when those increases are reflected in the calculation of the wage index. (We noted that this lag results from the fact that the wage index calculations rely on historical data.) We also agreed that addressing this systemic issue did not need to wait for comprehensive wage index reform given the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure (84 FR 19394 and 19395).

[142] As discussed in the FY 2020 IPPS final rule, the low wage index hospital policy was implemented in a budget neutral manner. In order to ensure that the overall effect of the application of the low wage index hospital policy was budget neutral, we applied a budget neutrality factor of 0.997987 to the FY 2020 standardized amount (84 FR 42667). The IPPS spending associated with the accounting statement in the FY 2020 IPPS final rule was approximately $113 billion. Applying the budget neutrality adjustment to the IPPS spending associated with the accounting statement results in roughly a $230 million impact of the low wage index hospital policy.

CHART 1. COMPARISON OF THE DISTRIBUTION OF THE PERCENTAGE CHANGE IN AHWS FROM FY 2019 TO FY 2021 FOR LOW WAGE INDEX HOSPITALS AND NON-LOW WAGE INDEX HOSPITALS



In general, the chart shows that the distribution of the changes in the average hourly wages of the low wage index hospitals (mean = 15.1%, standard deviation = 11.0%) is similar to the distribution of the changes in the average hourly wages of the non-low wage index hospitals (mean = 14.7%, standard deviation 8.9%). Although some low wage hospitals have indicated to us that they did use the increased payments they received under the low wage index hospital policy to increase wages more than they otherwise would have, the similarity in the two distributions indicates that, based on the audited wage data available to us, the policy has generally not yet had the effect of substantially reducing the wage index disparities that existed at the time the policy was promulgated. Also, to the extent that wage index disparities for a subset of low wage index hospitals has diminished, it is unclear to what extent that is attributable to the low wage index hospital policy given the effects of the COVID–19 PHE (as discussed below).

The COVID–19 PHE ended in May of 2023. With regard to the wage index,4 years is the minimum time before increases in employee compensation included in the Medicare cost report could be reflected in the wage index data. The first full fiscal year of wage data after the COVID–19 PHE is the FY 2024 wage data, which would be available for the FY 2028 IPPS/LTCH PPS rulemaking. As we explained earlier in this section, at the time the low wage index hospital policy was finalized, our intention was that it would be in effect for at least 4 fiscal years beginning October 1, 2019 and to revisit the issue of the duration of this policy as we gained experience under the policy. Because the effects of the COVID–19 PHE complicate our ability to evaluate the low wage index hospital policy and our ability to determine whether low wage hospitals have been provided a sufficient opportunity to increase employee compensation under the policy without the usual lag, we are proposing that the low wage index hospital policy and the related budget neutrality adjustment would be effective for at least three more years, beginning in FY 2025. This would result in the policy being in effect for at least 4 full fiscal years in total after the end of the COVID–19 PHE in May of 2023. This will allow us to gain experience under the policy for the same duration and in an environment more similar to the one we expected at the time the policy was first promulgated.

In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2025 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we are proposing to apply a budget neutrality adjustment in the same manner as we have applied it since FY 2020, as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.f. of the Addendum to this proposed rule for further discussion of the budget neutrality adjustment for FY 2025. For purposes of the low wage index hospital policy, based on the data for this proposed rule, the table displays the 25th percentile wage index value across all hospitals for FY 2025.

FY 2025 25th Percentile Wage Index Value	0.8879

6. Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a wage index cap policy and associated budget neutrality adjustment for FY 2023 and subsequent fiscal years. Under this policy, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. If a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index will not be less than 95 percent of the hospital's capped wage index in the prior FY. Except for newly opened hospitals, we apply the cap for a FY using the final wage index applicable to the hospital on the last day of the prior FY. A newly opened hospital will be paid the wage index for the area in which it is geographically located for its

first full or partial fiscal year, and it will not receive a cap for that first year, because it will not have been assigned a wage index in the prior year. The wage index cap policy is reflected at § 412.64(h)(7). We apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. For more information about the wage index cap policy and associated budget neutrality adjustment, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

For FY 2025, we would apply the wage index cap and associated budget neutrality adjustment in accordance with the policies adopted in the FY 2023 IPPS/LTCH PPS final rule. We note that the budget neutrality adjustment will be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this proposed rule for further information regarding the budget neutrality calculations.

H. FY 2025 Wage Index Tables

In this FY 2025 IPPS/LTCH PPS proposed rule, we have included the following wage index tables: Table 2 titled ''Case-Mix Index and Wage Index Table by CCN''; Table 3 titled ''Wage Index Table by CBSA''; Table 4A titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act''; and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the wage index tables for FY 2025.

I. Proposed Labor-Related Share for the FY 2025 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45208), we rebased and revised the hospital market basket to a 2018-based IPPS hospital market basket which replaced the 2014-based IPPS hospital market basket, effective beginning October 1, 2021. Using the 2018-based IPPS market basket, we finalized a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. In addition, in FY 2022, we implemented this revised and rebased labor-related share in a budget neutral manner (86 FR 45193, 86 FR 45529 through 45530). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204 through 45207), we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services. In this proposed rule, for FY 2025, we are not proposing to make any further changes to the labor-related share. For FY 2025, we are proposing to continue to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2024. We note that, consistent with our established frequency of rebasing the IPPS market basket every 4 years, we anticipate proposing to rebase and revise the IPPS market basket in the FY 2026 IPPS/LTCH PPS proposed rule. Our preliminary evaluation of more recent Medicare cost report data for IPPS hospitals for 2022 indicates that the major IPPS market basket cost weights (particularly the compensation and drug cost weights) are similar to those finalized in the 2018-based IPPS market basket.

As discussed in section V.B. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2025, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2025 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share. Table 1C, in section VI. of the Addendum to this FY 2025 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflects the

national labor-related share for hospitals located in Puerto Rico. For FY 2025, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2025, we are proposing to apply the wage index to a labor-related share of 67.6 percent of the national standardized amount.

IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2025 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the more commonly used method, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP).

A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

DSH Eligibility	Qualifying Criteria
Statutory Formula	A hospital that has a disproportionate patient percentage equal to or exceeding 15 percent may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.
''Pickle Method''	A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. We refer to these provisions collectively as section 3133 of the Affordable Care Act. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible for DSH payments under section 1886(d)(5)(F) of the Act receive 2 separately calculated payments:

Medicare DSH Payment	An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act.
Medicare DSH Uncompensated Care Payment	An uncompensated care payment determined as the product of 3 factors, as discussed in this section.

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress.[143] We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.'' In brief, the uncompensated care payment for an individual hospital is determined as the product of the following 3 factors:

Factor 1	75% of the total amount of DSH payments that would otherwise be made under section 1886(d)(5)(F) of the Act.
Factor 2	1 minus the percent change in the percent of individuals who are uninsured.
Factor 3	The hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that receive DSH payments, expressed as a percentage.

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or of the periods selected to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

The payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the empirically justified Medicare DSH payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to ''such subsection (d) hospitals'' the uncompensated care payment. Section 1886(r)(2)'s reference to ''such subsection (d) hospitals'' refers to hospitals that receive empirically justified Medicare DSH payments under section 1886(r)(1) for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we explained that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status (that is, eligibility to receive empirically justified Medicare DSH payments) for the applicable fiscal year (using the most recent data that are available). For this proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note that FY 2020 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing this proposed

[143] *https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/.*

rule.[144] If more recent data on DSH eligibility becomes available before the final rule, we would use such data in the final rule.

Our final determinations of a hospital's eligibility for uncompensated care and empirically justified Medicare DSH payments will be based on the hospital's actual DSH status at cost report settlement for FY 2025.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemakings for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. Eligible hospitals include the following:

- Subsection (d) Puerto Rico hospitals that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623 and 79 FR 50006).
- Sole community hospitals (SCHs) that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the fiscal year (based on the best available data at that time) subject to settlement through the cost report. If they receive interim empirically justified Medicare DSH payments in a fiscal year, they will also be eligible to receive interim uncompensated care payments for that fiscal year on a per discharge basis. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- Medicare-dependent, small rural hospitals (MDHs) are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals. Legislation has extended the MDH program into FY 2024. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

Section 307 of the Consolidated Appropriations Act, 2024 extended the MDH program through December 31, 2024. We will continue to make a determination concerning an MDH's eligibility for interim empirically justified Medicare DSH and uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.

- IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model, will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments until the Model's final performance year, which ends on December 31, 2025. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at *https://innovation.cms.gov/innovation-models/bpci-advanced.*
- IPPS hospitals that participate in the Comprehensive Care for Joint Replacement (CJR) Model's (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments We refer the reader to the final rule that appeared in the May 3, 2021, **Federal Register** (86 FR 23496), which extended the CJR Model for an additional three performance years. The Model's final performance year ends on December 31, 2024. For additional information on the CJR Model, we refer readers to the CMS website at *https://www.cms.gov/priorities/innovation/innovation-models/CJR.*
- Transforming Episode Accountability Model (TEAM) is a new proposed episode-based model, which is discussed in section X.A. of the preamble of this proposed rule. Hospitals participating in TEAM would continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The proposed model's start date is January 2026.

Ineligible hospitals include the following:

- Maryland hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1866(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, which concludes on December 31, 2026, Maryland hospitals are not paid under the IPPS and are ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- SCHs that are paid under their hospital-specific rate are not eligible for Medicare DSH and uncompensated care payments (78 FR 50623 and 50624).
- Hospitals participating in the Rural Community Hospital Demonstration Program are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).[145] The period of participation for the last hospital in the demonstration under this most recent legislative authorization will end on June 30, 2028. Under the payment methodology that applies during this most recent extension of the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are excluded from receiving interim and final uncompensated care payments. At the time of development of this proposed rule, we believe 23 hospitals may participate in the

[144] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

[145] The Rural Community Hospital Demonstration Program was extended for a subsequent 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). The period of performance for this 5-year extension period ended on December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114 255), enacted on December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the demonstration program for an additional 5-year period.

demonstration program at the start of FY 2025.

C. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the Secretary to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust subsection (d) hospitals' interim claim payments to an amount equal to 25 percent of what would have been paid if section 1886(r) of the Act did not apply. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments could be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

D. Supplemental Payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income insured days as a proxy for uncompensated care costs for these hospitals and to prevent undue long-term financial disruption for these providers. The regulations located at 42 CFR 412.106(h) govern the supplemental payment. In brief, the supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g)(1). The base year amount is the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable fiscal year (that is, FY 2025 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a fiscal year is determined as the product of Factor 1 and Factor 2 for that year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

We are not proposing any changes to the methodology for determining supplemental payments, and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals consistent with the methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and § 412.106(h).

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the eligibility and payment processes for the supplemental payment are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH PPS final rule. We note that the MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

E. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors, which are discussed in the next sections.

1. Proposed Calculation of Factor 1 for FY 2025

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. The regulations located at 42 CFR 412.106(g)(1)(i) govern the Factor 1 calculation. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, we would not know the precise aggregate empirically justified Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed. Thus, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. In brief, Factor 1 is the difference between the Secretary's estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of section 1886(r) of the Act; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act.

In this FY 2025 IPPS/LTCH PPS proposed rule, consistent with the policy that has applied since the FY 2014 final rule (78 FR 50627 through 50631), we are determining Factor 1 from the most recently available estimates of the aggregate amount of Medicare DSH payments that would be made for FY 2025 in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments that would be made for FY 2025, both as calculated by CMS' Office of the Actuary (OACT). Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in the FY 2025 IPPS/LTCH PPS final rule.

For this proposed rule, to calculate both estimates, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by OACT using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent DPPs and Medicare DSH payment adjustments provided in the IPPS Impact File. The projection of Medicare DSH payments for the fiscal year is also partially based on OACT's Part A benefits projection model, which projects, among other things, inpatient hospital spending. Projections of DSH payments additionally require projections of expected increases in

utilization and case-mix. The assumptions that were used in making these inpatient hospital spending, utilization, and case-mix projections and the resulting estimates of DSH payments for FY 2022 through FY 2025 are discussed later in this section and in the table titled ''Factors Applied for FY 2022 through FY 2025 to Estimate Medicare DSH Expenditures Using FY 2021 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2025 IPPS/LTCH PPS proposed rule, we used OACT's January 2024 Medicare DSH estimates, which were based on data from the December 2023 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2024 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2024 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are ineligible for empirically justified Medicare DSH payments and uncompensated care payments, they were excluded from the January 2024 Medicare DSH estimates. Because Maryland hospitals are not paid under the IPPS, they are also ineligible for empirically justified Medicare DSH payments and uncompensated care payments and were also excluded from OACT's January 2024 Medicare DSH estimates.

The 23 hospitals that CMS expects will participate in the Rural Community Hospital Demonstration Program in FY 2025 were also excluded from OACT's January 2024 Medicare DSH estimates because under the payment methodology that applies during the demonstration, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For this proposed rule, using the data sources as previously discussed, OACT's January 2024 estimates of Medicare DSH payments for FY 2025 without regard to the application of section 1886(r)(1) of the Act is approximately $13.943 billion. Therefore, also based on OACT's January 2024 Medicare DSH estimates, the estimate of empirically justified Medicare DSH payments for FY 2025, with the application of section 1886(r)(1) of the Act, is approximately $3.486 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2025). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, in this proposed rule, we are determining that Factor 1 for FY 2025 would be $10,457,250,000, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2025 ($13.943 billion minus $3.486 billion). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2025 IPPS/LTCH PPS final rule.

We note that the Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rules are generally consistent with those used for the Midsession Review of the President's Budget.[146] Consistent with historical practice, we expect that the Midsession Review will have updated economic assumptions and actuarial analysis, which will be used for the development of Factor 1 estimates in the FY 2025 IPPS/LTCH PPS final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available on the CMS website at *https://www.cms.gov/oact/tr/2023* under ''Downloads.'' [147] The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness. We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections (available at *https://www.cms.gov/data-research/research/actuarial-studies/actuarial-report-financial-outlook-medicaid*).

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by OACT's actuaries in determining our estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to estimate Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also includes descriptions of the ''Other'' and ''Discharges'' assumptions and provides additional information regarding how we address the Medicaid and CHIP expansion.

OACT's estimates for FY 2025 for this proposed rule began with a baseline of $13.400 billion in Medicare DSH expenditures for FY 2021. The following table shows the factors applied to update this baseline through the current estimate for FY 2025:

[146] As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget.*

[147] We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program.

FACTORS APPLIED FOR FY 2022 THROUGH FY 2025 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2021 BASELINE						
FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2022	1.025	0.946	0.997	0.9937	0.9607	12.873
2023	1.043	0.945	0.990	1.0503	1.0250	13.195
2024	1.031	0.977	1.005	1.0228	1.0349	13.656
2025	1.026	0.986	1.005	1.0046	1.0210	13.943

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The discharge figures for FY 2022 and FY 2023 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. We note that these claims data reflect the impact of the COVID–19 pandemic. The discharge figure for FY 2024 is based on preliminary data. The discharge figure for FY 2025 is an assumption based on recent historical experience, an assumed partial return to pre-COVID 19 trends, and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for FY 2022 to FY 2025 incorporate the actual impact and estimated future impact of the COVID–19 pandemic.

The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2022 and FY 2023 are based on actual claims data adjusted by a completion factor to account for incomplete claims data. We note that these claims data reflect the impact of the COVID–19 pandemic. The case-mix figures for FY 2024 and for FY 2025 are assumptions based on the 2012 ''Review of Assumptions and Methods of the Medicare Trustees' Financial Projections'' report by the 2010–2011 Medicare Technical Review Panel.[148]

The ''Other'' column reflects the change in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the estimated changes in Medicaid enrollment. Based on the most recent available data, Medicaid enrollment is estimated to be as follows: +8.3 percent in FY 2022, +5.1 percent in FY 2023, −13.9 percent in FY 2024, and −4.3 percent in FY 2025. In future IPPS rulemakings, our assumptions regarding Medicaid enrollment may change based on actual enrollment in the States.

We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid enrollee and, therefore, receive fewer hospital services.[149] Specifically, based on the most recent available data at the time of developing this proposed rule, OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be approximately 80 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary, due to the better health of these beneficiaries. The same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and thereafter due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion. In future IPPS rulemakings, the assumption about the average per-capita expenditures of Medicaid beneficiaries who enrolled due to the COVID–19 pandemic may change.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2022	2.7	-0.7	0.5	2.5
2023	4.1	-0.3	0.5	4.3
2024	3.3	-0.2	0.0	3.1
2025	3.0	-0.4	0.0	2.6

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year, except for the FY 2025 figures. The FY 2025 figures reflect the proposed inpatient hospital updates and productivity adjustment and are based on the 4th quarter 2023 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this proposed rule. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2025.

[148] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf.*

[149] For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available at *https://www.cms.gov/files/document/2018-report.pdf.*

We are inviting public comments on our proposed Factor 1 for FY 2025.

IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2025 (§ 412.106)

2. Calculation of Proposed Factor 2 for FY 2025

a. Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).

We are continuing to use the methodology that was used in FY 2018 through FY 2024 to determine Factor 2 for FY 2025—to use the National Health Expenditure Accounts (NHEA) data to determine the percent change in the percent of individuals who are uninsured. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198) for a complete discussion of the NHEA and why we determined, and continue to believe, that it is the data source for the rate of uninsurance that, on balance, best meets all our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate.

In brief, the NHEA represents the government's official estimates of economic activity (spending) within the health sector. The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html.*

To compute Factor 2 for FY 2025, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. For a complete discussion of the approach OACT used to prepare the NHEA's estimate of the rate of uninsurance in 2013, including the data sources used, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58998 and 58999).

The next metrics needed to compute Factor 2 for FY 2025 are projections of the rate of uninsurance in both CY 2024 and CY 2025. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2022 through 2031 and were published on June 14, 2023. Those projections used the latest NHEA historical data that were available at the time of their construction (that is, historical data through 2021). The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. For a complete discussion of how the NHEA data account for expected changes in enrollment across all the categories of insurance coverage previously listed, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58999).

b. Proposed Factor 2 for FY 2025

Using these data sources and the previously described methodologies, at the time of developing this proposed rule, OACT has estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent, and that the uninsured rates for CYs 2024 and 2025 were 8.5 percent and 8.8 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this FY 2025 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.[150]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we use a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we are continuing to apply the weighted average approach used in past fiscal years to estimate this proposed rule's rate of uninsurance for FY 2025.

OACT certified the estimate of the rate of uninsurance for FY 2025 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. We note that we may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2025. The calculation of the proposed Factor 2 for FY 2025 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2024: 8.5 percent.
- Percent of individuals without insurance for CY 2025: 8.8 percent.
- Percent of individuals without insurance for FY 2025 (0.25 times 0.085) + (0.75 times 0.088): 8.7 percent.

$1 - |((0.14 - 0.087)/0.14)| = 1 - 0.3786 = 0.6214$ (62.14 percent).

We are proposing that Factor 2 for FY 2025 would be 62.14 percent.

The proposed FY 2025 uncompensated care amount is equivalent to proposed Factor 1 multiplied by proposed Factor 2, which is $6,498,135,150.00.

We are inviting public comments on our proposed Factor 2 for FY 2025.

3. Calculation of Proposed Factor 3 for FY 2025

a. General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

[150] *https://www.cms.gov/files/document/certification-rates-uninsured-2025-proposed-rule.pdf.*

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary for us to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. For a discussion of the methodology, we used to calculate Factor 3 for fiscal years 2014 through 2022, we refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 59001 and 59002).

b. Background on the Methodology Used To Calculate Factor 3 for FY 2023 and Subsequent Years

Section 1886(r)(2)(C) of the Act governs the selection of the data to be used in calculating Factor 3 and allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634 through 50647), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments for a fiscal year and for those hospitals that we do not estimate will qualify for Medicare DSH payments for that fiscal year but that may ultimately qualify for Medicare DSH payments for that fiscal year at the time of cost report settlement.

As described in the FY 2022 IPPS/LTCH PPS final rule, commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of historical data from Worksheet S–10 data of the Medicare cost report (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, we stated that we would consider using multiple years of data when the vast majority of providers had been audited for more than 1 fiscal year under the revised reporting instructions. Audited FY 2019 cost reports were available for the development of the FY 2023 IPPS/LTCH PPS proposed and final rules. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2019 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49036 through 49047), we finalized a policy of using a multi-year average of audited Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years. We explained our belief that this approach would be generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Under this policy, we used a 2-year average of audited FY 2018 and FY 2019 Worksheet S–10 data to calculate Factor 3 for FY 2023. We also indicated that we expected FY 2024 would be the first year that 3 years of audited data would be available at the time of rulemaking. For FY 2024 and subsequent fiscal years, we finalized a policy of using a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, if a hospital does not have data for all 3 years used in the Factor 3 calculation, we will determine Factor 3 based on an average of the hospital's available data. For IHS and Tribal hospitals and Puerto Rico hospitals, we use the same multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2024 and subsequent fiscal years as is used to determine Factor 3 for all other DSH-eligible hospitals (in other words, hospitals eligible to receive empirically justified Medicare DSH payments for a fiscal year) to determine Factor 3.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49033 through 49047), we also modified our policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent fiscal year to determine uncompensated care costs for the subsequent fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we finalized our proposal to use the hospital's most recent prior cost report, if that cost report spans the applicable period.[151]

(1) Scaling Factor

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59003), we continued the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) to address the effects of calculating Factor

[151] For example, in determining Factor 3 for FY 2023, we did not use the same cost report to determine a hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we used the cost report that spanned the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and used the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spanned some portion of FY 2018.

3 using data from multiple fiscal years, in which we apply a scaling factor to the Factor 3 values calculated for all DSH-eligible hospitals so that total uncompensated care payments to hospitals that are projected to be DSH-eligible for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Pursuant to that policy, we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH-eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year.

(2) New Hospital Policy for Purposes of Factor 3

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59003), we continued our new hospital policy that was modified in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) and initially adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 through 42371) to determine Factor 3 for new hospitals. Consistent with our policy of using multiple years of cost reports to determine Factor 3, we defined new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Under this definition, the cut-off date for the new hospital policy is the beginning of the fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2024, the FY 2020 cost reports were the most recent year of cost reports for which audits of Worksheet S–10 data had been conducted. Thus, hospitals with CMS Certification Numbers (CCNs) established on or after October 1, 2020, were subject to the new hospital policy for FY 2024.

Under our modified new hospital policy, if a new hospital has a preliminary projection of being DSH-eligible based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments because we would have no uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement. In FY 2024, while we continued to determine the numerator of the Factor 3 calculation using the new hospital's uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the current fiscal year, we determined Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. In addition, we applied a scaling factor to the Factor 3 calculation for a new hospital.[152]

(3) Newly Merged Hospital Policy

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59004), we continued our policy of treating hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021 and 50022), we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals.

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59004), we stated that we would continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the methodology used to determine Factor 3 for new hospitals described in section IV.E.3. of the preamble of this proposed rule, we continued our policy for determining Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we apply a scaling factor, as discussed in section IV.E.3. of the preamble of this proposed rule, to the Factor 3 calculation for a newly merged hospital. In the FY 2024 IPPS/LTCH PPS final rule, we explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule.

(4) CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59004 through 59005), we continued the policy of trimming CCRs, which we adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49043), for FY 2024. Under this policy, we apply the following steps to determine the applicable CCR separately for each fiscal year that is included as part of the multi-year average used to determine Factor 3:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including hospitals that are not DSH-eligible), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

[152] In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we explained our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, to improve consistency and predictability across all hospitals.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including hospitals that are not DSH-eligible), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling'').

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing these steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

(5) Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant uncompensated care costs (UCC) that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for any fiscal year that is included as a part of the multi-year average are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year.[153]

However, we note that we have audited the Worksheet S–10 data that will be used in the Factor 3 calculation for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), we determined it is unnecessary to apply the UCC trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In rare cases, hospitals that are not currently projected to be DSH-eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59004), we stated that in addition to the UCC trim methodology, we will continue to apply an alternative trim specific to certain hospitals that do not have audited Worksheet S–10 data for one or more of the fiscal years that are used in the Factor 3 calculation. For FY 2023 and subsequent fiscal years, in the rare case that a hospital's insured patients' charity care costs for a fiscal year are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we will not calculate a Factor 3 for the hospital at the time of proposed or final rulemaking. This trim will only impact hospitals that are not currently projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for hospitals projected to be DSH-eligible. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we will apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59005), we also stated that we would continue to use a threshold of 3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continued to believe these thresholds are appropriate to address potentially aberrant data. We also continued to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051). In addition, we continued our policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044) of applying the same threshold amounts originally calculated for the FY 2018 reports to identify potentially aberrant data for FY 2024 and subsequent fiscal years to facilitate transparency and predictability. If a hospital subject to this trim is determined to be DSH-eligible at cost report settlement, the MAC will calculate the hospital's Factor 3 using the same methodology used to calculate Factor 3 for new hospitals.

c. Methodology for Calculating Factor 3 for FY 2025

For FY 2025, consistent with § 412.106(g)(1)(iii)(C)(*11*), we are following the same methodology as applied in FY 2024 and described in the previous section of this proposed rule: to determine Factor 3 using the most recent 3 years of audited cost reports, from FY 2019, FY 2020, and FY 2021. Consistent with our approach for FY 2024, for FY 2025, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of this proposed rule. For purposes of this FY 2025 IPPS/LTCH PPS proposed rule, we are using reports from the December 2023 HCRIS extract to calculate Factor 3. We intend to use the March 2024 update of HCRIS to calculate the final Factor 3 for the FY 2025 IPPS/LTCH PPS final rule.

Thus, for FY 2025, we will use 3 years of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, including IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, following these steps:

Step 1: Select the hospital's longest cost report for each of the most recent 3 years of fiscal year (FY) audited cost reports (FY 2019, FY 2020, and FY 2021). Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous fiscal year spanned the more recent fiscal year, the previous fiscal year cost report will be used in this step. In the rare case that using a previous fiscal year cost report results in

[153] For example, if a hospital's FY 2018 cost report is determined to include potentially aberrant data, data from its FY 2019 cost report would be used for the ratio calculation.

a period without a report, we would use the prior year report, if that cost report spanned the applicable period.[154] In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that spans the relevant fiscal year.

Step 2: Annualize the UCC from Worksheet S–10 Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for all DSH-eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on cost report data from the most recent 3 years of audited cost reports (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor, as discussed in the previous section of this proposed rule.

For purposes of identifying new hospitals, for FY 2025, the FY 2021 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CCNs established on or after October 1, 2021, will be subject to the new hospital policy in FY 2025. If a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2025, the hospital will receive an uncompensated care payment calculated using a Factor 3 where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2025 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2021 cost reports for all DSH-eligible hospitals. In addition, we will apply a scaling factor, as discussed previously, to the Factor 3 calculation for a new hospital. As we explained in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59004), we believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, to improve consistency and predictability across all hospitals.

For FY 2025, the eligibility of a newly merged hospital to receive interim uncompensated care payments will be based on whether the surviving CCN has a preliminary projection of being DSH-eligible, and the amount of any interim uncompensated care payments will be based on the uncompensated care costs from the FY 2019, FY 2020, and FY 2021 cost reports available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2025 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2025 cost report. The denominator will be the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2021 cost reports for all DSH-eligible hospitals, which is the most recent fiscal year for which audits have been conducted. We will also apply a scaling factor, as described previously.

Under the CCR trim methodology, for purposes of this FY 2025 proposed rule, the statewide average CCR was applied to 10 hospitals' FY 2019 reports, of which 4 hospitals had FY 2019 Worksheet S–10 data. The statewide average CCR was applied to 8 hospitals' FY 2020 reports, of which 3 hospitals had FY 2020 Worksheet S–10 data. The statewide average CCR was applied to 8 hospitals' FY 2021 reports, of which 3 hospitals had FY 2021 Worksheet S–10 data.

For a hospital that is subject to either of the trims for potentially aberrant data (the UCC trim and alternative trim methodology explained in the previous section of this proposed rule) and is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment will be calculated only after the hospital's reporting of insured charity care costs on its FY 2025 Worksheet S–10 has been reviewed. Accordingly, the MAC will calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2025 cost report. Then we will calculate Factor 3 for the hospital using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator will reflect the uncompensated care costs reported on the hospital's FY 2025 cost report, while the denominator will reflect the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2021 cost reports of all DSH-eligible hospitals. In addition, we will apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital.

For purposes of the FY 2025 IPPS/LTCH PPS final rule, consistent with our Factor 3 methodology since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50642), we intend to use data from the March 2024 HCRIS extract for this calculation, which will be the latest quarterly HCRIS extract that is publicly available at the time of the development of the FY 2025 IPPS/LTCH PPS final rule.

Regarding requests from providers to amend and/or reopen previously audited Worksheet S–10 data for the most recent 3 cost reporting years that are used in the methodology for calculating Factor 3, we note that MACs follow normal timelines and procedures. For purposes of the Factor 3 calculation for the FY 2025 IPPS/LTCH PPS final rule, any amended reports and/or reopened reports would need to have completed the amended report and/or reopened report submission processes by the end of March 2024. In other words, if the amended report and/or reopened report is not available for the March HCRIS extract, then that amended and/or reopened report data will not be part of the FY 2025 IPPS/LTCH PPS final rule's Factor 3 calculation. We note that the March HCRIS data extract will be available during the comment period for this proposed rule if providers want to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

d. Per-Discharge Amount of Interim Uncompensated Care Payments for FY 2025 and Subsequent Fiscal Years

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per-discharge basis. Typically, we use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

[154] For example, if a hospital does not have a FY 2020 cost report because the hospital's FY 2019 cost report spanned the FY 2020 time period, we will use the FY 2019 cost report that spanned the FY 2020 time period for this step. Using the same example, where the hospital's FY 2019 report is used for the FY 2020 time period, we will use the hospital's FY 2018 report if it spans some of the FY 2019 time period. We will not use the same cost report for both the FY 2020 and the FY 2019 time periods.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45247 and 45248), we modified this calculation for FY 2022 to be based on an average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average using the most recent 3 years of discharge data, which would have included data from FY 2018, FY 2019, and FY 2020. We explained our belief that computing a 3-year average with FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the COVID–19 pandemic. For the same reason, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49045), we calculated interim uncompensated care payments based on the 3-year average of discharges from FY 2018, FY 2019, and FY 2021 rather than a 3-year average using the most recent 3 years of discharge data.

We explained in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59010) that believed that computing a 3-year average using the most recent 3 years of discharge data would potentially underestimate the number of discharges for FY 2024 due to the effects of the COVID–19 pandemic during FY 2020, which was the first year of the COVID–19 pandemic. We considered using an average of FY 2019, FY 2021, and FY 2022 discharge data to calculate the per-discharge amount for interim uncompensated care payments for FY 2024. However, we agreed with commenters that using FY 2019 data may overestimate discharge volume because updated claims data used to estimate the FY 2024 discharges in the Factor 1 calculation indicated that discharge volumes were not expected to return to pre-pandemic levels during FY 2024. Therefore, for FY 2024, we finalized a policy of calculating the per-discharge amount for interim uncompensated care payments using an average of FY 2021 and FY 2022 discharge data.

For FY 2025 and subsequent fiscal years, we are proposing to calculate the per-discharge amount for interim uncompensated care payments using the average of the most recent 3 years of discharge data. Accordingly, for FY 2025, we propose to use an average of discharge data from FY 2021, FY 2022, and FY 2023. We believe that our proposed approach will likely result in a better estimate of the number of discharges during FY 2025 and subsequent years for purposes of the interim uncompensated care payment calculation.

As we explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50645), we believe that it is appropriate to use a 3-year average of discharge data to reduce the degree to which we would over- or under-pay the uncompensated care payment on an interim basis. In any given year, a hospital could have low or high Medicare utilization that differs from other years. For example, if a hospital had two Medicare discharges in its most recent year of claims data but experienced four discharges in FY 2025, during the fiscal year, we would pay two times the amount the hospital should receive and need to adjust for that at cost report settlement. Similarly, if a hospital had four Medicare discharges in its most recent year of claims data, but experienced two discharges in FY 2025, during the fiscal year, we would only pay half the amount the hospital should receive and need to adjust for that at cost report settlement.

We also believe that, generally, use of the most recent 3 years of discharge data, rather than older data, is more likely to reflect current trends in discharge volume and provide an approximate estimate of the number of discharges in the applicable fiscal year. In addition, we note that including discharge data from FY 2023 to compute this 3-year average is consistent with the proposed use of FY 2023 Medicare claims in the IPPS ratesetting, as discussed in section I.E. of the preamble of this FY 2025 IPPS/LTCH PPS proposed rule.

Under this proposal, the resulting 3-year average of the most recent years of available historical discharge data would be used to calculate a per-discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2025 and subsequent fiscal years. The interim uncompensated care payments made to a hospital during the fiscal year will be reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the fiscal year.

We are proposing to make conforming changes to the regulations under 42 CFR 412.106. Specifically, we are proposing to modify paragraph (1) of § 412.106(i) to state that for FY 2025 and subsequent fiscal years, interim uncompensated care payments will be calculated based on an average of the most recent 3 years of available historical discharge data. We are requesting comments on this proposal.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process through which a hospital may submit a request to its MAC for a lower per-discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment at cost report settlement if the per-discharge amount is not lowered (for example, recoupment of 10 percent or more of the hospital's total uncompensated care payment, or at least $100,000). For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per-discharge uncompensated care payment amount. As another example, a hospital might request that its per-discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 through 58834), the hospital's MAC will evaluate these requests and the supporting documentation before the beginning of the fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected discharges for the current fiscal year. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per-discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per-discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the fiscal year. We are continuing to apply this policy for FY 2025.

We refer readers to the Addendum in the FY 2023 IPPS/LTCH final rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation (87 FR 49431 through 49432). No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per-

discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

e. Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this proposed rule, we will publish on the CMS website a table listing Factor 3 for hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2025 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 10 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals have 60 days from the date of public display of this FY 2025 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with this proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process.[155] Comments raising issues or concerns that are specific to the information included in the table and supplemental data file should be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov.* We will address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2025 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposals for FY 2025 must be submitted in one of the three ways found in the **ADDRESSES** section of the proposed rule before the close of the comment period in order to be assured consideration. In addition, we note that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2025 (§ 412.106)

F. Impact on Medicare DSH Payment Adjustment of Proposed Implementation of New OMB Labor Market Delineations

As discussed in section III.B. of the preamble of this proposed rule, we are proposing to implement the new OMB labor market area delineations (which are based on 2020 Decennial Census data) for the FY 2025 wage index. This proposal also would have an impact on the calculation of Medicare DSH payment adjustments to certain hospitals. Hospitals that are designated as rural with less than 500 beds and are not rural referral centers (RRCs) or Medicare-dependent, small rural hospitals (MDHs) are subject to a maximum DSH payment adjustment of 12 percent. Accordingly, hospitals with less than 500 beds that are currently in urban counties that would become rural if we finalize our proposal to adopt the new OMB delineations, and that do not become RRCs or MDHs, would be subject to a maximum DSH payment adjustment of 12 percent. (We note, as discussed in section V.F.2. of the preamble of this proposed rule, under current law the MDH program will expire on December 31, 2024). We also note that urban hospitals are only subject to a maximum DSH payment adjustment of 12 percent if they have less than 100 beds.

Our existing regulations at 42 CFR 412.102 will apply in FY 2025 with respect to the calculation of the DSH payments to hospitals that are currently located in urban counties that would become rural if we finalize our proposal to adopt the new OMB delineations. The provisions of 42 CFR 412.102 specify that a hospital located in an area that is reclassified from urban to rural (as defined in the regulations), as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for two successive fiscal years. Specifically, the regulations state that, in the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two thirds of the difference between the disproportionate share payments as applicable to the hospital before its redesignation from urban to rural and disproportionate share payments otherwise, applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its redesignation from urban to rural and disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

G. Withdrawal of 42 CFR 412.106 (FY 2004 and Prior Fiscal Years) to the Extent It Included Only ''Covered Days'' in the SSI Ratio

In *Becerra* v. *Empire Health Foundation, for Valley Hospital Medical Center,* 597 U.S. 424 (2022) (*Empire Health*), the Supreme Court addressed the question of whether Medicare patients remain ''entitled to benefits under part A'' when Medicare does not pay for their care, such as when they have exhausted their Medicare benefits for a spell of illness. Prior to fiscal year (FY) 2005, when we calculated a hospital's DSH adjustment we included in the Medicare fraction (also referred to as the Medicare-SSI fraction, SSI fraction, or SSI ratio) only ''covered'' Medicare patient days, that is, days paid by Medicare. 42. CFR 412.106(b)(2)(i) (2003). The ''covered'' days rule originated in the FY 1986 IPPS interim final rule (51 FR 16,772 and 16,788) and originally appeared in § 412.106(a)(1)(i) but was later re-numbered. The approach of excluding from the Medicare fraction patient days for which Medicare did not pay was based on an interpretation of the statute's parenthetical phrase ''(for such days).''

Section 1886(d)(5)(F)(vi)(I) of the Act. Following a series of judicial decisions rejecting a parallel interpretation of the same language in the numerator of the Medicaid fraction as counting only patient days actually paid by the Medicaid program, the Secretary revisited that approach in a 2004 rulemaking. Thus, the ''covered days'' rule was the relevant Medicare payment policy until it was revised and replaced

[155] For example, if the report does not reflect audit results due to MAC mishandling, or the most recent report differs from a previously accepted, amended report due to MAC mishandling.

by the FY 2005 IPPS final rule (69 FR 48,916, 49,099, and 49,246).

The FY 2005 regulation at issue in *Empire Health*—codified in the FY 2005 IPPS final rule—interpreted the statute to mean that the Medicare fraction includes non-covered days in the SSI ratio. (For more information see 69 FR 48916, 49099, and 49246 (amending 42 CFR 412.106(b)(2)(i) to include in the Medicare fraction all days associated with patients who were entitled to Medicare Part A during their hospital stays, regardless of whether Medicare paid for those days).) In *Empire Health,* the Supreme Court upheld the FY 2005 regulation and held that the statute ''disclose[s] a surprisingly clear meaning,'' 597 U.S. at 434, namely that beneficiaries remain ''entitled to benefits under part A'' on days for which Medicare does not pay and thus the Medicare fraction includes total days, not only covered days. The Supreme Court also definitively resolved the meaning of the parenthetical phrase ''(for such days)'' in the Medicare fraction, rejecting the provider's contention that the phrase changed the consistent meaning of ''entitled to benefits under Part A'' from ''meeting Medicare's statutory (age or disability) criteria on the days in question,'' to ''actually receiving Medicare payments.'' *Id.* at 440. The Court determined that the ''for such days'' parenthetical ''instead works as HHS says: hand in hand with the ordinary statutory meaning of 'entitled to [Part A] benefits.' '' *Id.*

The Supreme Court has concluded that the interpretation set forth in the FY 2005 IPPS final rule ''correctly construes the statutory language at issue.'' *Empire Health,* 597 U.S. at 434. Because the pre-FY 2005 rule conflicts with the plain meaning of the statute, as confirmed by the Supreme Court, it cannot govern the calculation of DSH payments for hospitals with properly pending claims in DSH appeals or open cost reports that include discharges that need to be determined pursuant to the statute, regardless of whether such discharges would otherwise pre-date the change in the regulation finalized by the FY 2005 IPPS final rule. For that reason, we are proposing to formally withdraw 42 CFR 412.106 as it existed prior to the effective date of the FY 2005 IPPS final rule to the extent it included only covered days in the SSI ratio. We will apply the statute as understood by the Supreme Court in *Empire Health,* instead of the pre-FY 2005 regulation, to any properly pending claim in a DSH appeal or open cost report to which that regulation would otherwise have applied. We do not believe this change constitutes an exercise of our ''retroactive'' rulemaking authority under section 1871(e)(1)(A) of the Act. Rather, we will apply the plain meaning of the statute (as it has existed unchanged, in relevant part, since its enactment on April 7, 1986). Moreover, because we are applying the substantive legal standard established by the statute itself, and not filling any gap therein, notice-and-comment rulemaking is not required by section 1871(e)(1)(A) of the Act, as construed in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (June 3, 2019).

The withdrawal of this regulation will not serve as a basis to reopen a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, or a decision by the Provider Reimbursement Review Board or the Administrator. We recognize that hospitals may have anticipated receiving greater Medicare reimbursement for still-open pre-FY 2005 cost reporting periods in circumstances where the ''covered'' days limitation would have resulted in a larger DSH adjustment. However, we are obliged to apply the statute as the Supreme Court determined Congress wrote it.

V. Other Decisions and Changes to the IPPS for Operating System

A. Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to (Fixed-Loss Outlier threshold for Nontransfer Cases adjusted for geographic variations in costs/ Geometric Mean Length of Stay for the MS–DRG) * (Length of Stay for the Case plus 1 day).

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute at subparagraph 1886(d)(5)(J) of the Act directs CMS to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6))). For an MS–DRG to qualify for the special payment methodology, the geometric mean

length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018, as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment.

2. Proposed Changes for FY 2025

As discussed in section II.D. of the preamble of this proposed rule, based on our analysis of FY 2023 MedPAR claims data, we are proposing to make changes to a number of MS–DRGs, effective for FY 2025. Specifically, we are proposing to do the following:

- Adding ICD–10–PCS codes describing left atrial appendage closure (LAAC) procedures and cardiac ablation procedures to proposed new MS–DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation).
- Delete existing MS–DRGs 453, 454, and 455 (Combined Anterior and Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively) and to reassign procedures from the existing MS–DRGs, 453, 454, and 455 and MS–DRGs 459 and 460 (Spinal Fusion except Cervical with MCC and without MCC, respectively) to proposed new MS–DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical), proposed new MS–DRGs 426, 427, and 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC, with CC, without MCC/CC, respectively), proposed new MS–DRGs 429 and 430 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC and without MCC, respectively), and proposed new MS–DRGs 447 and 448 (Multiple Level Spinal Fusion Except Cervical with MCC, and without MCC, respectively). We note that we are also proposing to revise the title of MS–DRGs 459 and 460 to ''Single Level Spinal Fusion Except Cervical with MCC and without MCC, respectively''.
- Reassign cases that report a principal diagnosis of acute leukemia with an ''other'' O.R. procedure from MS–DRGs 834, 835, and 836 (Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to proposed new MS–DRG 850 (Acute Leukemia with Other O.R. Procedures). We note that we are also proposing to revise the title of MS–DRGs 834, 835, and 836 from ''Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC'', respectively to ''Acute Leukemia with MCC, with CC, and without CC/MCC''.

The proposed revised MS–DRGs 459 and 460 are currently subject to the postacute care transfer policy. We believe it is appropriate to reevaluate the postacute care transfer policy status for MS–DRGs 459 and 460. When proposing changes to MS–DRGs that involve adding, deleting, and reassigning procedures between proposed new and revised MS–DRGs, we continue to believe it is necessary to evaluate all of the affected MS–DRGs to determine whether they should be subject to the postacute care transfer policy.

MS–DRGs 834, 835, and 836 are currently not subject to the postacute care transfer policy. While we are proposing to reassign certain cases from these MS–DRGs to newly proposed MS–DRGs, we have estimated that less than 5 percent of the current cases would shift from the current assigned MS–DRGs to the proposed new MS–DRGs. We do not consider these proposed revisions to constitute a material change that would warrant reevaluation of the postacute care status of MS–DRGs 834, 835, and 836. CMS may further evaluate what degree of shifts in cases for existing MS–DRGs warrant consideration for the review of postacute care transfer and special payment policy status in future rulemaking.

In light of the proposed changes to the MS–DRGs for FY 2025, according to the regulations under § 412.4(d), we have evaluated the MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2023 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to assess new MS–DRGs and reassess revised MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG.

Proposed new MS–DRGs 426, 427, 447, and 448 would qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. As described in the regulations at § 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. We therefore propose to add proposed new MS–DRGs 426, 427, 428, 447, and 448 to the list of MS–DRGs that are subject to the postacute care transfer policy.

MS–DRGs 459 and 460 are currently subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, as proposed to be revised, would not qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We therefore propose to remove proposed revised MS–DRGs 459 and 460 from the list of MS–DRGs that are subject to the postacute care transfer policy if the proposed changes to these MS–DRGs are finalized.

Using the December 2023 update of the FY 2023 MedPAR file, we have developed the following chart which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS–DRGs. For the FY 2025 final rule, we intend to update this analysis using the most recent available data at that time.

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LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2025							
Proposed New or Revised MS-DRG	**MS-DRG Title**	**Total Cases**	**Postacute Care Transfer Cases (55th percentile: 1,056)**	**Short-Stay Postacute Care Transfer Cases**	**Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 10.178%)**	**FY 2024 Postacute Transfer Policy Status**	**Proposed Postacute Care Transfer Policy Status**
317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	1,842	311*	14	0.8%*	New	No
402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical	17,032	6,778	718	4.2%*	New	No
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	2,833	2,285	764	27%	New	Yes
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	13,259	8,047	2,313	17.4%	New	Yes
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	8,329	3,482	329	4.0%*	New	Yes**
429	Combined Anterior and Posterior Cervical Spinal Fusion with MCC	622	484*	172	27.7%	New	No
430	Combined Anterior and Posterior Cervical Spinal Fusion without MCC	1,872	968*	128	6.8%*	New	No
447	Multiple Level Spinal Fusion Except Cervical with MCC	2,200	1,814	778	35.4%	New	Yes
448	Multiple Level Spinal Fusion	15,496	8,376	1,673	10.8%	New	Yes

	Except Cervical without MCC						
459	Single Level Spinal Fusion Except Cervical with MCC	1,170	897*	286	24.4%	Yes	No
460	Single Level Spinal Fusion Except Cervical without MCC	14,830	6,355	750	5.1%*	Yes	No
850	Acute Leukemia with Other Procedures	384	139*	46	12%	New	No

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

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During our annual review of proposed new or revised MS–DRGs and analysis of the December 2023 update of the FY 2023 MedPAR file, we reviewed the list of proposed revised or new MS–DRGs that qualify to be included on the list of MS–DRGs subject to the postacute care transfer policy for FY 2025 to determine if any of these MS–DRGs would also be subject to the special payment methodology policy for FY 2025. We note that MS–DRGs 459 and 460 are not currently subject to the special payment policy, and as we are proposing to remove them from the list of MS–DRGs subject to the postacute care transfer policy if the proposed changes to those MS–DRGs are finalized, no further evaluation of special payment policy is necessary.

Based on our analysis of proposed changes to MS–DRGs included in this proposed rule, we determined that proposed new MS–DRGs 426, 427, and 447 meet the criteria for the MS–DRG special payment methodology. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we are proposing that MS–DRGs 426, 427, 428, 447, 448, would be subject to the MS–DRG special payment methodology, effective for FY 2025. For the FY 2025 final rule, we intend to update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2025

Proposed New or Revised MS-DRG	MS-DRG Title	Geometric Mean Length of Stay	Average Charges of 1-Day Discharges	50 Percent of Average Charges for all Cases within MS-DRG	FY 2024 Special Payment Policy Status	Proposed Special Payment Policy Status
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	7.7	$244,471	$236,394	New	Yes
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	4	$211,714	$156,062	New	Yes
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	2.6	$214,986	$107,493	New	Yes*
447	Multiple Level Spinal Fusion Except Cervical with MCC	8.1	$163,042	$145,144	New	Yes
448	Multiple Level Spinal Fusion Except Cervical without MCC	3.2	$149,862	$89,091	New	Yes*

* As described in the policy at 42 CFR 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the special payment transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

B. Proposed Changes in the Inpatient Hospital Update for FY 2025 (§ 412.64(d))

1. Proposed FY 2025 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2025, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2024. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2025 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket of every 3 years. In compliance with section 404 of the of Public Law 108–173, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022. Consistent with our established frequency of rebasing the IPPS market basket every 4 years, we plan on proposing to rebase and revise the IPPS market basket in the FY 2026 IPPS/LTCH PPS proposed rule. We note that our preliminary evaluation of more recent Medicare cost report data for IPPS hospitals for 2022 indicates that the major IPPS market basket cost weights (particularly the compensation and drug cost weights) are similar to those finalized in the 2018-based IPPS market basket.

We are proposing to base the FY 2025 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2023, which is estimated to be 3.0 percent. We also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2025 market basket update in the final rule.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term MFP with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment, to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2025, we are proposing a productivity adjustment of 0.4 percent. Similar to the proposed market basket rate-of-increase, for this proposed rule, the estimate of the proposed FY 2025 productivity adjustment is based on IGI's fourth quarter 2023 forecast. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2025 productivity adjustment for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2025, as specified in the following table:

PROPOSED FY 2025 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality

data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment.

As discussed in section V.F. of the preamble of this proposed rule, section 4102 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), enacted on December 29, 2022, extended the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024). Subsequently, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, further extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Under current law, the MDH program will expire for discharges on or after January 1, 2025. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

For FY 2025, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.6 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.35 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.85 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.4 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As previously discussed, we are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the market basket update and the productivity adjustment in the final rule.

2. Proposed FY 2025 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2025, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2023, for this FY 2025 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing a market basket update of 3.0 percent less a productivity adjustment of 0.4 percentage point. Therefore, for FY 2025, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2025 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing a FY 2025 applicable percentage increase to the operating standardized amount of 2.6 percent (that is, the FY 2025 estimate of the proposed market basket rate-of-increase of 3.0 percent less 0.4 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing a FY 2025 applicable percentage increase to the operating standardized amount of 0.35 percent (that is, the FY 2025 estimate of the proposed market basket rate-of-increase of 3.0 percent, less an adjustment of 2.25 percentage points (the proposed market basket rate-of-increase of 3.0 percent × 0.75 for failure to be a meaningful EHR user), and less 0.4 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2025 market basket update and the productivity adjustment for the FY 2025 IPPS/LTCH PPS final rule.

PROPOSED FY 2025 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS UNDER THE IPPS

FY 2025	Hospital is a Meaningful EHR User	Hospital is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**

C. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999 through 46000), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47087), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- Number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2025 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2025 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2023 (October 1, 2022 through September 30, 2023), and include bills posted to CMS' records through December 2023. We believe that this is the best available data for use in calculating the proposed national and regional median CMI values and is consistent with our proposal to use the FY 2023 MedPAR claims data for FY 2025 ratesetting.

In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2024, they must have a CMI value for FY 2023 that is at least—

- 1.7764 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals

(excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table. We intend to update the proposed CMI values in the FY 2025 IPPS/LTCH PPS final rule to reflect the updated FY 2023 MedPAR file, which will contain data from additional bills received through March 2024.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.49655
2. Middle Atlantic (PA, NJ, NY)	1.5563
3. East North Central (IL, IN, MI, OH, WI)	1.6427
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7216
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6306
6. East South Central (AL, KY, MS, TN)	1.59315
7. West South Central (AR, LA, OK, TX)	1.7814
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7804
9. Pacific (AK, CA, HI, OR, WA)	1.7821

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2025, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2022 (that is, October 1, 2021 through September 30, 2022), which are the latest cost report data available at the time this proposed rule was developed. We believe that this is the best available data for use in calculating the proposed median number of discharges by region and is consistent with our data proposal to use cost report data from cost reporting periods beginning during FY 2022 for FY 2025 ratesetting. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2024, must have, as the number of discharges for its cost reporting period that began during FY 2022, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. We refer readers to the proposed number of discharges as set forth in the following table. We intend to update these numbers in the FY 2025 final rule based on the latest available cost report data.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,889
2. Middle Atlantic (PA, NJ, NY)	9,922
3. East North Central (IL, IN, MI, OH, WI)	7,592
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	6,728
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,096
6. East South Central (AL, KY, MS, TN)	8,093
7. West South Central (AR, LA, OK, TX)	5,806
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	7,775
9. Pacific (AK, CA, HI, OR, WA)	8,571

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

3. Qualification Under the Discharge Criterion for Osteopathic Hospitals

Section 1886(d)(5)(C) of the Act sets forth certain criteria that must be met for a hospital to be classified as a rural

referral center, including a discharge criterion specifying the hospital has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the region in which the hospital is located. Section 9106 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) amended section 1886(d)(5)(C) of the Act to provide for a separate discharge criterion for an osteopathic hospital to qualify for classification as a rural referral center, effective for cost reporting periods beginning on or after January 1, 1986. To implement this statutory provision, in the FY 1987 IPPS final rule, we revised 42 CFR 412.96(c)(2) to specify that for cost reporting periods beginning on or after January 1, 1986 an osteopathic hospital, recognized by the American Osteopathic Hospital Association, that is located in a rural area must have at least 3,000 discharges during its most recently completed cost reporting period to meet the number of discharges criterion (51 FR 31471). In the FY 1996 IPPS final rule, in light of a name change of the American Osteopathic Hospital Association to the American Osteopathic Healthcare Association, we subsequently revised 42 CFR 412.96(c)(2) to specify that the osteopathic hospital must be recognized by the American Osteopathic Healthcare Association ''(or any successor organization)'' (60 FR 45810).

As we discussed in implementing the number of discharges criterion for osteopathic hospitals in the FY 1987 IPPS final rule, ''[b]ecause section 1886(d)(5)(C)(i) of the Act specifically limits this qualification to osteopathic hospitals, we do not believe that this standard should apply to all hospitals'' (51 FR 31473). Accordingly, to qualify under this lower number of discharges criterion, a hospital must be an osteopathic hospital. It has come to the attention of CMS that the successor organization to the American Osteopathic Healthcare Association, namely the Accreditation Commission for Health Care, accredits acute care hospitals, including hospitals that are not osteopathic. Thus, a hospital receiving an accreditation letter or certificate from the successor organization is not necessarily an osteopathic hospital. We are therefore proposing to revise the regulations at 42 CFR 412.96(c)(2) to clarify that, to qualify for RRC classification based on the lower discharge criterion for osteopathic hospitals, a hospital must be an osteopathic hospital and by itself recognition (such as an accreditation letter) by a successor organization to the American Osteopathic Healthcare Association is not necessarily sufficient to demonstrate that a hospital is an osteopathic hospital.

We propose to amend our regulations at 42 CFR 412.96 by revising paragraph (c)(2)(ii) as follows: ''(ii) For cost reporting periods beginning on or after January 1, 1986, an osteopathic hospital, recognized by the American Osteopathic Healthcare Association (or any successor organization), that is located in a rural area must have at least 3,000 discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section to meet the number of discharges criterion. A hospital applying for rural referral center status under the number of discharges criterion in this paragraph must demonstrate its status as an osteopathic hospital.''

Consistent with section 1886(d)(5)(C)(i) of the Act, evidence of osteopathic status may include, but is not limited to, the hospital's scope of services and its mix of medical specialties. CMS will consider the totality of the information demonstrating whether an applicant hospital is an osteopathic hospital. We seek comment on additional types of evidence we should consider in the determination of a hospital's osteopathic status.

D. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The low-volume hospital payment adjustment is implemented in the regulations at 42 CFR 412.101. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act, and is based on the per discharge amount paid to the qualifying hospital. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. The payment adjustment for low-volume hospitals is not budget neutral.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59041 through 59045), section 4101 of the CAA, 2023 (Pub. L. 117–328) extended through FY 2024 the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals in effect for FYs 2019 through 2022. The Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for a portion of FY 2025. Specifically, section 306 of the CAA, 2024 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through December 31, 2024. Beginning January 1, 2025, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 and discussed later in this section, will resume. We discuss the proposed payment policies for FY 2025 in section V.E.2. in the preamble of this proposed rule.

TABLE V.E.-01: LOW-VOLUME HOSPITAL QUALIFYING CRITERIA AND PAYMENT ADJUSTMENT FOR FYs 2019 AND SUBSEQUENT FYs

Fiscal Years	Road Miles	Total Discharges	Payment Adjustment
2019 through 2024 and 2025 discharges through 12/31/24	>15	<= 500	0.25
		> 500 < 3,800	0.25 - [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200)
2025 discharges beginning 1/1/25 and subsequent years	>25	< 200	0.25

2. Extension of Temporary Changes to Low-Volume Hospital Payment Definition and Payment Adjustment Methodology and Conforming Changes to Regulations

As discussed previously, section 4101 of the CAA, 2023 modified the definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) of the Act through September 30, 2024. Prior to the enactment of the CAA, 2024 (Pub. L. 118–42), the temporary changes to the low-volume hospital qualifying criteria and payment adjustment provided by section 4101 of CAA, 2023 were set to expire on October 1, 2024. Section 306 of the CAA, 2024 extends the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024 (that is, for discharges occurring before January 1, 2025).

Under section 1886(d)(12)(C)(i) of the Act, as amended by Public Law 118–42, for FYs 2019 through 2024 and the portion of FY 2025 occurring before January 1, 2025, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. In accordance with the existing regulations at § 412.101(a), we define the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1). Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FY 2019 through December 31, 2024, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), we specified a continuous, linear sliding scale formula to determine the low volume payment adjustment, as reflected in the regulations at § 412.101(c)(3)(ii). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. For qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment is calculated using the formula at § 412.101(c)(3)(ii) (which is shown in the Table V.E.–01). For this purpose, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges). The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low volume payment adjustment in the current year (§ 412.101(b)(2)(iii)). The low-volume hospital payment adjustment for FYs 2019 through 2024 is set forth in the regulations at § 412.101(c)(3).

Consistent with the extension of the methodology for calculating the payment adjustment for low-volume hospitals through FY 2024, we are proposing to continue using the previously specified continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for the portion of FY 2025 occurring before January 1, 2025. We are also proposing to make conforming changes to the regulation text in § 412.101 to reflect the extensions of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals in accordance with provisions of the CAA, 2024. Specifically, we are proposing to make conforming changes to paragraphs (b)(2)(iii) and (c)(3) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for the portion of FY 2025 through December 31, 2024, is the same low-volume hospital payment adjustment policy in effect for FYs 2019 through 2024 (as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399) and in the FY 2024 IPPS/LTCH final rule (88 FR 59041 through 59045)). In addition, in accordance with the provisions of the CAA, 2024, we are proposing to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for the portion of FY 2025 beginning on January 1, 2025 and for subsequent fiscal years, the low-volume hospital payment adjustment policy will revert back to the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described in section V.E.3. of this preamble. We further propose that if the temporary changes to the low-volume payment adjustment are extended through legislation beyond December 31, 2024, we would make the conforming changes to the regulations at § 412.101 (b)(2)(i),

(b)(2)(iii), (c)(1), and (c)(3) to reflect any further extension.

3. Proposed Payment Adjustment for the Portion of FY 2025 Beginning on January 1, 2025, and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended by section 306 of the CAA, 2024, beginning with FY 2025 discharges occurring on or after January 1, 2025, the low-volume hospital definition and payment adjustment methodology will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Specifically, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010, FY 2025 discharges occurring on or after January 1, 2025 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals.

Therefore, effective for the portion of FY 2025 beginning on January 1, 2025 and subsequent years, under current policy at § 412.101(b), to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For the portion of FY 2025 beginning on January 1, 2025, and subsequent years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As discussed previously, for FYs 2005 through 2010 and FY 2019 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through 2024) from another subsection (d) hospital. Accordingly, for FY 2025 and subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). As previously noted, we are proposing to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for the portion of FY 2025 beginning on January 1, 2025, and subsequent fiscal years, the low-volume hospital payment adjustment policy is the same as that in effect for FYs 2005 through 2010.

On average, approximately 600 hospitals per year were eligible for the low-volume hospital payment adjustment for FYs 2019 through 2024 under the temporary changes in the low-volume hospital payment policy as amended by section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), and section 4101 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328). As discussed previously, the CAA, 2024 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through December 31, 2024. Therefore, for the portion of FY 2025 beginning on January 1, 2025 and for subsequent years the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Based on historical data for hospitals that qualified during FYs 2005—2010, we estimate that fewer than 10 hospitals would qualify for the low-volume hospital payment adjustment for the portion of FY 2025 beginning on January 1, 2025 under current law.

5. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment FY 2025

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59044 through 59045), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge

determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

In addition to the discharge criterion, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in section 1886(d)(12)(C)(i) of the Act, which is codified at § 412.101(b)(2), for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2025 beginning October 1, 2024 through December 31, 2024, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital, as reflected in proposed revised § 412.101(b)(2). Additionally, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for the portion of FY 2025 beginning January 1, 2025 through September 30, 2025, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospital(s), location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2025, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for the portion of FY 2025 beginning October 1, 2024 through December 31, 2024, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2024, in order for the low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2024. If a hospital's written request for low-volume hospital status for the portion of FY 2025 beginning October 1, 2024 through December 31, 2024 is received after September 1, 2024, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2025 discharges beginning October 1, 2024 through December 31, 2024, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Additionally, we are proposing that a hospital must also submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital continues to meet the applicable mileage and discharge criteria for the portion of FY 2025 beginning on January 1, 2025 through September 30, 2025 (as described earlier). Specifically, for the portion of FY 2025 beginning on January 1, 2025, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than December 1, 2024, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after January 1, 2025. If a hospital's written request for low-volume hospital status for the portion of FY 2025 beginning on January 1, 2025 is received after December 1, 2024, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2025 discharges on or after January 1, 2025, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

A hospital may choose to make a single written request for low-volume hospital status to its MAC for both the portion of FY 2025 beginning on October 1, 2024 and ending December 31, 2024 and the portion of FY 2025 beginning on January 1, 2025 through September 30, 2024 by the September 1, 2024 deadline discussed previously. Alternatively, a hospital may choose to submit separate written requests, one for the portion of FY 2025 beginning on October 1, 2024 and ending on December 31, 2024 (by the September 1, 2024 deadline discussed previously), and another for the portion of FY 2025 beginning on January 1, 2025 through September 30, 2025 (by the December 1, 2024 deadline discussed previously).

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2024 may continue to receive a low-volume hospital payment adjustment for FY 2025 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2025 (that is, the discharge criterion and mileage criterion for the period beginning October 1, 2024 through December 31, 2024, as well as the discharge criterion and mileage criterion for the period beginning on January 1, 2025 through September 30, 2025, respectively). As discussed previously, for the portion of FY 2025 beginning on January 1, 2025, the discharge and the mileage criteria are reverting to the statutory requirements that were in effect prior to FY 2011, and to the preexisting low-

volume hospital qualifying criteria, as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i). As in previous years, we are proposing that such a hospital must send written verification that is received by its MAC no later than September 1, 2024 or December 1, 2024, respectively, stating that it meets the mileage criterion for the applicable portion(s) of FY 2025, as described previously. For example, for the portion of FY 2025 beginning October 1, 2024 through December 31, 2024, the hospital must state it is located more than 15 road miles from the nearest ''subsection (d)'' hospital. Similarly, for the portion of FY 2025 beginning on January 1, 2025, the hospital must state it is located more than 25 road miles from the nearest ''subsection (d)'' hospital. For FY 2025, we are further proposing that this written verification must also state, based upon the most recently submitted cost report, that the hospital meets the discharge criterion for the applicable portion(s) of FY 2025, as described previously. For example, for the portion of FY 2025 beginning October 1, 2024 through December 31, 2024, the hospital must have less than 3,800 discharges total, including both Medicare and non-Medicare discharges. Similarly, for the portion of FY 2025 beginning on January 1, 2025, the hospital must have less than 200 discharges total, including both Medicare and non-Medicare discharges. If a hospital's request for low-volume hospital status for FY 2025 is received after September 1, 2024, (or after December 1, 2024 for the portion of FY 2025 beginning on January 1, 2025) and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume add-on payment adjustment to determine the payment for the hospital's discharges for the applicable portion(s) FY 2025, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

E. Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As discussed in section V.B. of the preamble of this proposed rule, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Under current law, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire for discharges on or after January 1, 2025. Beginning with discharges occurring on or after January 1, 2025, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program had been extended by subsequent legislation as follows: section 606 of the American Taxpayer Relief Act (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Section 106 of the Protecting Access to Medicare Act (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Section 205 of the MACRA (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). Section 50205 of the Bipartisan Budget Act (Pub. L. 115–123) extended the MDH program through FY 2022 (that is for discharges occurring before October 1, 2022). Section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180) extended the MDH program through December 16, 2022. Section 102 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229) extended the MDH program through December 23, 2022. Section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) extended the MDH program through FY 2024 (that is for discharges occurring before October 1, 2024). Lastly, under current law, section 307 of the CAA, 2024 (Pub. L. 118–42) extended the MDH program through December 31, 2024 (that is, for discharges occurring before January 1, 2025).

For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); the August 2015 interim final rule with comment period (80 FR 49596); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57054 through 57057); the FY 2018 notice (83 FR 18303 through 18305); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429); and the FY 2024 IPPS/LTCH PPS final rule (88 FR 59045).

2. Implementation of Legislative Extension of MDH Program

Prior to the enactment of Public Law 118–42, under section 4102 of Public Law 117–328, the MDH program authorized by section 1886(d)(5)(G) of the Act was set to expire at the end of FY 2024. Section 307 of Public Law 118–42 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''October 1, 2024'' and inserting ''January 1, 2025''. Section 307 of Public Law 118–42 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

Therefore, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2024.

As a result of the extension of the MDH program through December 31, 2024 as provided by section 307 of Public Law 118–42, a provider that is classified as an MDH as of September 30, 2024, will continue to be classified as an MDH as of October 1, 2024, with no need to reapply for MDH classification.

3. Expiration of the MDH Program

Because section 307 of the CAA, 2024 extended the MDH program through December 31, 2024 only, beginning January 1, 2025, the MDH program will no longer be in effect. Since the MDH program is not authorized by statute beyond December 31, 2024, beginning January 1, 2025, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate. There are currently 173 MDHs, of which we estimate 114 would have been paid under the blended payment of the Federal rate and hospital-specific rate while the remaining 59 would have

been paid based on the IPPS Federal rate. With the expiration of the MDH program, all these providers will all be paid based on the IPPS Federal rate beginning with discharges occurring on or after January 1, 2025.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (b)(2)(v). Specifically, the existing regulations at § 412.92(b)(2)(i) and (b)(2)(v) allow for an effective date of an approval of SCH status that is the day following the expiration date of the MDH program. We note that these same conditions apply to MDHs that intend to apply for SCH status with the expiration of the MDH program on December 31, 2024. Therefore, in order for an MDH to receive SCH status effective January 1, 2025, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program; that is, the MDH must apply for SCH status by December 2, 2024. The MDH also must request that, if approved as an SCH, the SCH status be effective with the expiration of the MDH program; that is, the MDH must request that the SCH status, if approved, be effective January 1, 2025, immediately after its MDH status expires with the expiration of the MDH program on December 31, 2024. We emphasize that an MDH that applies for SCH status in anticipation of the expiration of the MDH program would not qualify for the January 1, 2025 effective date for SCH status if it does not apply by the December 2, 2024 deadline. If the MDH does not apply by the December 2, 2024 deadline, the hospital would instead be subject to the usual effective date for SCH classification as specified at § 412.92(b)(2)(i); that is, as of the date the MAC receives the complete application from the provider.

As noted, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through December 31, 2024. We are further proposing that if the MDH program were to be extended by law beyond December 31, 2024, similar to how it was extended by prior legislation as described previously, we would, depending on timing of such legislation in relation to the final rule, modify our proposed conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect any such further extension of the MDH program. These modifications to our proposed conforming changes would only be made if the MDH program were to be extended by statute beyond December 31, 2024.

F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes in the Balanced Budget Act of 1997 (Pub. L. 105–33). Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME cannot exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)

a. Overview

CMS has increased the overall number of slots available to teaching hospitals on several previous occasions. Notably, Congress authorized Medicare payment for one thousand additional FTE GME resident slots in section 126(a) of the Consolidated Appropriations Act, 2021, adding paragraph 1886(h)(9) to the Act. Most recently, section 4122(a) of the CAA, 2023 amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of additional residency positions (also referred to as slots) to hospitals. Section 1886(h)(10)(A) of the Act requires that for FY 2026, the Secretary shall initiate an application round to distribute 200 residency positions. At least 100 of the positions made available under section 1886(h)(10)(A) shall be distributed for psychiatry or psychiatry subspecialty residency training programs. The Secretary is required, subject to certain

provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31, 2026, and the increase is effective beginning July 1, 2026.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(10)(B)(i) of the Act requires the Secretary to take into account the ''demonstrated likelihood'' of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(10)(B)(ii) of the Act requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals. Stated briefly, and discussed in greater detail later in this proposed rule, the categories are as follows: (1) hospitals located in rural areas or that are treated as being located in a rural area (pursuant to sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act); (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Section 1886(h)(10)(F)(iii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(10)(B)(iii) of the Act further requires that each qualifying hospital that submits a timely application receive at least 1 (or a fraction of 1) of the residency positions made available under section 1886(h)(10) of the Act before any qualifying hospital receives more than 1 residency position.

Section 1886(h)(10)(C) of the Act places certain limitations on the distribution of the residency positions. First, a hospital may not receive more than 10 additional full-time equivalent (FTE) residency positions. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the hospital agrees to increase the total number of FTE residency positions under the approved medical residency training program of the hospital by the number of positions made available to that hospital. Third, if a hospital that receives an increase to its otherwise applicable resident limit under section 1886(h)(10) of the Act is eligible for an increase to its otherwise applicable resident limit under 42 CFR 413.79(e)(3) (or any successor regulation), that hospital must ensure that residency positions received under section 1886(h)(10) of the Act are used to expand an existing residency training program and not for participation in a new residency training program.

b. Determinations Required for the Distribution of Residency Positions

(1) Determination That a Hospital Has a ''Demonstrated Likelihood'' of Filling the Positions

Section 1886(h)(10)(B)(i) of the Act directs the Secretary to take into account the ''demonstrated likelihood'' of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary. In accordance with section 1886(h)(10)(A)(iv) of the Act, the increase would be effective beginning July 1 of the fiscal year of the increase; therefore, additional residency positions under section 1886(h)(10) of the Act would be effective July 1, 2026.

Consistent with the application cycle established for section 126 of the CAA, 2021 (86 FR 73419 through 73445) we are proposing that the application deadline for the additional positions made available for a fiscal year be March 31 of the prior fiscal year; that is, for FY 2026, the application deadline would be March 31, 2025. Accordingly, all references in this section to the application deadline are references to the application deadline of March 31, 2025.

We are proposing that a hospital show a ''demonstrated likelihood'' of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program. In order to be eligible for additional positions, the new program or expansion of an existing program could not begin prior to July 1, 2026, the effective date of the section 4122 residency positions.

In order to demonstrate that a hospital does not have sufficient room under its current FTE resident cap(s) for purposes of the prioritization discussed at section c.3. of this preamble, if applicable, we are proposing that a hospital would be required to submit copies of its most recently submitted Worksheet E, Part A and Worksheet E–4 from the Medicare cost report (CMS-Form- 2552–10) as part of its application for an increase to its FTE resident cap(s). The hospital would demonstrate and attest to a planned new program or expansion of an existing program by meeting at least one of the following two ''Demonstrated Likelihood'' criteria:

• ''*Demonstrated Likelihood*'' *Criterion 1 (New Residency Program).* The hospital does not have sufficient room under its FTE resident cap, is not a rural hospital eligible for an increase to its cap under 42 CFR 413.79(e)(3) (or any successor regulation), and intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital's first 5 training years beginning on or after the effective date of the increase). Under ''Demonstrated Likelihood'' Criterion 1, the hospital will be required to meet at least one of the following conditions as part of its application:

++ Application for accreditation of the new residency program has been submitted to the Accreditation Council for Graduate Medical Education (ACGME) (or application for approval of the new residency program has been submitted to the American Board of Medical Specialties (ABMS)) by the application deadline.

++ The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of site visit) by the application deadline.

• ''*Demonstrated Likelihood*'' *Criterion 2 (Expansion of an Existing Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first 5 training years beginning on or after the date the increase would be effective. Under ''Demonstrated Likelihood'' criterion 2, the hospital will be required to meet at least one of the following conditions as part of its application:

++ The hospital has received approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

++ The hospital has submitted a request by the application deadline for

a permanent complement increase of the existing residency program.

++ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

Under ''Demonstrated Likelihood'' Criterion 2, the hospital is applying for an increase in its FTE resident cap because it is expanding an existing residency program. We are proposing this means that as of the application deadline the hospital is either already training residents in this program, or, if the program exists at another hospital as of that date, the residents will begin to rotate to the applying hospital on or after the effective date of the increase. In addition, we note that section 1886(h)(10)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital's FTE resident cap increases, based on the newly awarded positions under section 4122 of CAA, 2023. Therefore, we are proposing that a hospital must, as part of its application, attest to increasing the number of its residency positions by the amount of the hospital's FTE resident cap increase based on any newly awarded positions, in accordance with the provisions of section 1886(h)(10)(B)(i) of the Act.

(2) Determination That a Hospital Is Located or Treated as Being Located in a Rural Area (Category One)

Section 1886(h)(10)(B)(ii) of the Act requires the Secretary to distribute not less than 10 percent of resident positions available for distribution to each of four categories of hospitals. Under section 1886(h)(10)(B)(ii)(I) of the Act, the first of these categories consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area (pursuant to section 1886(d)(8)(E) of the Act). We refer to this category as Category One. We note that the definition of Category One for purposes of section 4122 of the CAA, 2023 mirrors the definition of Category One included under section 1886(h)(9)(B)(ii)(I) for purposes of section 126 of the CAA, 2021. Therefore, we are proposing to determine Category One eligibility as discussed in the final rule implementing section 126 of the CAA, 2021 (86 FR 73422 through 73424).

For purposes of determining whether a hospital is considered rural, we are proposing to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, or successor files containing similar information, from the most recent FY IPPS final rule (or correction notice if applicable). This file will be available on the CMS website in approximately August 2024, the year prior to the year of the application deadline, March 31, 2025. Under the file's current format, blank cells in Columns D and E indicate an area outside of a CBSA.

Under section 1886(d)(8)(E) of the Act, a subsection (d) hospital (that is, generally, an IPPS hospital) that is physically located in an urban area is treated as being located in a rural area for purposes of payment under the IPPS if it meets criteria specified in section 1886(d)(8)(E)(ii) of the Act, as implemented in the regulations at § 412.103. Under these regulations, a hospital may apply to CMS to be treated as located in a rural area for purposes of payment under the IPPS. Given the fixed number of available residency positions, it is necessary to establish a deadline by which a hospital must be treated as being located in a rural area for purposes of Category One. We are proposing to use Table 2, or a successor table containing similar information, posted with the most recent IPPS final rule, available on the CMS website in approximately August 2024, (or correction notice if applicable), to determine whether a hospital is reclassified to rural under § 412.103. If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the March 31, 2025 application deadline, the hospital would submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

(3) Determination of Hospitals for Which the Reference Resident Level of the Hospital Is Greater Than the Otherwise Applicable Resident Limit (Category Two)

Under section 1886(h)(10)(B)(ii)(II) of the Act, the second category consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(10)(F)(iv) of the Act) is greater than the otherwise applicable resident limit. We refer to this category as Category Two. We note the definition of Category Two under section 1886(h)(10)(B)(ii)(II) of the Act mirrors the definition of Category Two under section 1886(h)(9)(B)(ii)(II), section 126 of the CAA, 2021. Therefore, we are proposing to determine Category Two eligibility as discussed in the final rule implementing section 126 of the CAA, 2021 (86 FR 73424 through 73425) with adjustments to consider the provisions of sections 126, 127, and 131 of the CAA, 2021, as discussed later.

Under section 1886(h)(10)(F)(iv) of the Act, the term 'reference resident level' means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of section 1886(h)(10) of the Act, December 29, 2022, for which a cost report has been settled (or, if not, submitted (subject to audit)), as discussed in this proposed rule.

Under section 1886(h)(10)(F)(v) of the Act, the term 'resident level' has the meaning given such term in paragraph (7)(C)(i). That section defines ''resident level'' as with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

Under section 1886(h)(10)(F)(i) of the Act, the term 'otherwise applicable resident limit' means, ''with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to the changes made by this provision of the CAA, 2023, but taking into account section 1886(h)(7)(A), (7)(B), (8)(A), (8)(B), and (9)(A)'' of the Act. These cross-referenced sub-paragraphs all address the distribution of positions and redistribution of unused positions.

As finalized for purposes of section 126 of the CAA, 2023, the ''reference resident level'' refers to a hospital's allopathic and osteopathic FTE resident count for a specific period. The definition can vary based on what calculation is being performed to determine the correct allopathic and osteopathic FTE resident count (see, for example, 42 CFR 413.79(c)(1)(ii)) (86 FR 73424)). As noted previously, section 4122 of the CAA, 2023, under new section 1886(h)(10)(F)(iv) of the Act defines the ''reference resident level'' as coming from the most recent cost reporting period of the hospital ending on or before the date of enactment of the CAA, 2023 (that is, December 29, 2022).

Under new section 1886(h)(10)(F)(i) of the Act, the term ''otherwise applicable resident limit'' is defined as ''the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph [that is, section 1886(h)(10) of the Act], but taking into

account paragraphs (7)(A), (7)(B), (8)(A), (8)(B), and (9)(A).'' In the FY 2022 IPPS/LTCH PPS final rule (86 FR 25505), we finalized for purposes of section 126 of the CAA, 2021, the definition of ''otherwise applicable resident limit'' as the hospital's 1996 cap during its reference year, adjusted for the following: ''new medical residency training programs'' as defined at § 413.79(l); participation in a Medicare GME affiliation agreement as defined at §§ 413.75(b) and referenced at 413.79(f); participation in an Emergency Medicare GME affiliation agreement as defined at § 413.79(f); participation in a hospital merger; whether an urban hospital has a separately accredited rural training track program as defined at § 413.79(k); applicable decreases or increases under section 422 of the MMA, applicable decreases or increases under section 5503 of the Affordable Care Act, and applicable increases under section 5506 of the Affordable Care Act. For purposes of section 4122 of the CAA, 2023, we are proposing to use this same definition of ''otherwise applicable resident limit'' and adding to this definition the following: applicable increases or adjustments under sections 126, 127, and 131 of the CAA, 2021.

Regarding the term ''resident level'', in the CY 2011 OPPS final rule (75 FR 46391) we indicated that we generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as the hospital's resident level, which we are proposing to define consistently with the definition in section 4122 of the CAA, 2023; that is, the ''resident level'' under section 1886(h)(7)(c)(i) of the Act, which is defined as the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph 1886(h)(4) of the Act), in the fields of allopathic and osteopathic medicine for the hospital.

For the purposes of section 4122 of the CAA, 2023 we are proposing that the definitions of the terms ''otherwise applicable resident limit,'' ''reference resident level,'' and ''resident level'' should be as similar as possible to the definitions those terms have in the regulations at § 413.79(c), as initially set out in the CY 2011 OPPS rulemaking, as revised for purposes of section 126 of the CAA, 2021 (86 FR 73424) with adjustments made to the definition of ''otherwise applicable resident limit'' for sections 126, 127, and 131 of the CAA, 2021.

(4) Determination of Hospitals Located in States With New Medical Schools, or Additional Locations and Branch Campuses (Category Three)

The third category specified in section 1886(h)(10)(B)(ii)(III) of the Act, as added by section 4122 of CAA, 2023, consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME) or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). We note that the statutory language is specific with respect to these definitions. We refer to this category as Category Three. We note that the definition of Category Three for purposes of section 4122 of the CAA, 2023, mirrors the definition of Category Three included under section 1886(h)(9)(B)(ii)(III) of the Act for purposes of section 126 of the CAA, 2021. Therefore, we are proposing to determine Category Three eligibility as discussed in the final rule implementing section 126 of the CAA, 2021 (86 FR 73425 through 73426).

We are proposing that the hospitals located in the following 35 States and one territory, referred to as Category Three States, would be considered Category Three hospitals: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. If a hospital is located in a State not listed here, but it believes the State in which it is located should be on this list, the hospital may submit a formal comment on this proposed rule to make a change to this list, or must provide documentation with submission of its application to CMS that the State in which it is located has a medical school or additional location or branch campus of a medical school established on or after January 1, 2000. Pursuant to the statutory language, all hospitals in such states are eligible for consideration; the hospitals, themselves, do not need to meet the conditions of section 1886(h)(10)(B)(ii)(III)(aa) or (bb) of the Act in order to be considered.

(5) Determination of Hospitals That Serve Areas Designated as Health Professional Shortage Areas Under Section 332(a)(1)(A) of the Public Health Service Act (Category Four)

The fourth category specified in the law consists of hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary. Category Four for section 4122 of the CAA, 2023 mirrors the definition of Category Four included under section 1886(h)(9)(B)(ii)(IV) for purposes of implementing section 126 of the CAA, 2021. Therefore, we are proposing to determine Category Four eligibility as discussed in the final rule implementing section 126 of the CAA, 2021 (86 FR 73426 through 73430).

We are proposing that an applicant hospital qualifies under Category Four if it participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental-health-only geographic HPSA. Specific to mental-health-only geographic HPSAs, we are proposing that the program must be a psychiatry program or a subspecialty of psychiatry. In addition, a Category Four hospital must submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, that it meets the requirement that residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental-health-only geographic HPSA.

(6) Determination of a Qualifying Hospital

Section 1886(h)(10)(F)(iii) of the Act defines a ''qualifying hospital'' as ''a hospital described in any of the subclauses (I) through (IV) of subparagraph (B)(ii).'' As such, and consistent with the definition of ''qualifying hospital'' used for purposes of section 126 of the CAA, 2021 (86 FR 73430 through 73431), we are proposing to define a qualifying hospital as a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

c. Number of Residency Positions Made Available to Hospitals and Limitation on Individual Hospitals

(1) Number of Residency Positions Made Available and Distribution for Psychiatry or Psychiatry Subspecialty Residencies

Section 1886(h)(10)(A)(ii) of the Act limits the aggregate number of total new residency positions made available in FY 2026 across all hospitals to no more than 200. Section 1886(h)(10)(A)(iii) of the Act further specifies that at least 100 of the positions made available under section 1886(h)(10) must be distributed for a psychiatry or psychiatry subspecialty residency. The phrase ''psychiatry or psychiatry subspecialty residency'' is defined at section 1886(h)(10)(F)(ii) of the Act to mean ''a residency in psychiatry as accredited by the Accreditation Council for Graduate Medical Education (ACGME) for the purpose of preventing, diagnosing, and treating mental health disorders.''

We are proposing that of the total residency slots distributed under section 4122 of the CAA, 2023, at least 100 but not more than 200 slots would be distributed to hospitals applying for residency programs in psychiatry and psychiatry subspecialties. For purposes of determining which programs are considered psychiatry subspecialties, we are proposing to refer to the list included on ACGME website at *https://www.acgme.org/* under the ''Specialties'' tab, currently: Addiction Medicine, Addiction Psychiatry, Brain Injury Medicine, Child and Adolescent Psychiatry, Consultation-Liaison Psychiatry, Forensic Psychiatry, Geriatric Psychiatry, Hospice and Palliative Medicine, and Sleep Medicine. We note that the ACGME list of psychiatry subspecialties may change, and we are proposing that the list of psychiatry subspecialties included on the ACGME website at the time of application submission would guide determination of which programs CMS would consider psychiatry subspecialties. In accordance with statute, the subspecialty would have to be accredited with psychiatry as a core specialty. We are also proposing that the remaining non-psychiatric slots would be awarded to other approved medical residency programs under 42 CFR 413.75(b).

(2) Pro Rata Distribution and Limitation on Individual Hospitals

As noted earlier in this preamble, section 1886(h)(10)(B)(iii) of the Act requires that each qualifying hospital that submits a timely application under subparagraph 1886(h)(10)(A) of the Act would receive at least 1 (or a fraction of 1) of the positions made available under section 1886(h)(10) of the Act before any qualifying hospital receives more than 1 of such positions. Section 1886(h)(10)(C)(i) of the Act limits a qualifying hospital to receiving no more than 10 additional FTEs from those authorized under section 1886(h)(10) of the Act. As stated earlier in this preamble, we are proposing that a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories. For purposes of distributing residency slots under section 4122 of the CAA, 2023, we are proposing to first distribute slots by prorating the available 200 positions among all qualifying hospitals such that each qualifying hospital receives up to 1.00 FTE, that is, 1.00 FTE or a fraction of 1.00 FTE. We are proposing that if residency positions are awarded based on a fraction of 1.00 FTE, each qualifying hospital would receive the same FTE amount. Consistent with the number of decimal places used for the FTE slots awards in other distributions such as section 126 of the CAA, 2021, we are proposing to prorate the slot awards under section 4122 of the CAA, 2023, rounded to two decimal places. The table later in this section provides examples of how the 200 slots would be prorated based on the number of qualifying applicants. Given the limited number of residency positions available and the number of hospitals we expect to apply, we are proposing that a hospital may not submit more than one application under section 4122 of the CAA, 2023.

Number of Qualifying Applicants	Pro Rata Share of 200 FTEs
180	1.00
200	1.00
350	0.57
1,000	0.20

We refer readers to section I.O.6. of Appendix A of this proposed rule where we discuss an alternative we considered for the distribution of slots under section 4122 of the CAA, 2023.

(3) Prioritization of Applications by HPSA Score

If any residency slots remain after distributing up to 1.00 FTE to each qualifying hospital, we will prioritize the distribution of the remaining slots based on the HPSA score associated with the program for which each hospital is applying. Taking an example from the table in the previous section, if 180 qualifying hospitals apply under section 4122 of the CAA, 2023, each qualifying hospital would receive 1.00 FTE and the 20 remaining residency positions would be prioritized for distribution based on the HPSA score associated with the program for which each hospital is applying. We are proposing the HPSA prioritization methodology will be the methodology we finalized for purposes of section 126 of the CAA, 2021 (86 FR 73434 through 73440). We believe including such a prioritization will further support the training of residents in underserved and rural areas thereby helping to address physician shortages and the larger issue of health inequities in these areas. Using this HPSA prioritization method, we are proposing to limit a qualifying hospital's total award under section 4122 of the CAA, 2023, to 10.00 additional FTEs, consistent with section 1886(h)(10)(C)(i) of the Act. Consistent with the methodology we use for implementing section 126 of the CAA, 2021, as part of determining eligibility for additional slots, we would compare the hospital's FTE resident count to its adjusted FTE resident cap on the cost report worksheets submitted with its application. If the hospital's FTE count is below its adjusted FTE cap, the hospital would be ineligible for its full FTE request, because the facility had not yet fully utilized the already-allotted slots. We note that in calculating the adjusted FTE cap we do not consider adjustments for Medicare GME Affiliation Agreements since these adjustments are temporary.

As finalized under section 126 of the CAA, 2021 (86 FR 73435), for purposes of prioritization under section 4122 of

the CAA, 2023, primary care and mental-health-only population and geographic HPSAs apply. As discussed in the final rule implementing section 126 of the CAA, 2021, each year in November, prior to the beginning of the application period, CMS will request HPSA ID and score information from HRSA so that recent HPSA information is available for use for the application period. CMS will only use this HPSA information, HPSA ID's and their corresponding HPSA scores, in order to review and prioritize applications. To assist hospitals in preparing for their applications, the HPSA information received from HRSA will also be posted when the online application system becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.* The information will also be posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.* Click on the link on the left side of the screen associated with the appropriate final rule home page or ''Acute Inpatient—Files for Download'' (86 FR 73445).

Given that residency slots under section 4122 of the CAA, 2023 are to be distributed in FY 2026, we are proposing that the HPSA IDs and scores used for the prioritization of slots, if applicable, would be the same HPSA IDs and scores used for the prioritization of slots under round 4 of section 126 of the CAA, 2021. This group would include HPSAs that are in designated or proposed for withdrawal status at the time the HPSA information is received from HRSA. As noted in section j. of this preamble, CMS will request HPSA data from HRSA in November 2024 to be used for purposes of section 4122 of the CAA, 2023.

(4) Requirement for Rural Hospitals To Expand Programs

Section 1886(h)(10)(C)(iii) of the Act requires that if a hospital that receives an increase in the otherwise applicable resident limit under section 1886(h)(10) of the Act would be eligible for an adjustment to the otherwise applicable resident limit for participation in a new medical residency training program under 42 CFR 413.79(e)(3) (or any successor regulation), the hospital shall ensure that any positions made available under this paragraph are used to expand an existing program of the hospital, and not be utilized for new medical residency training programs. Under the regulations at 42 CFR 413.79(e)(3), a rural hospital may receive an increase to its cap for participating in training residents in a new program, which is effective after a 5-year cap-building period for that new program. We note that if a rural hospital were to receive a cap increase for a new program under the 5-year cap-building period as well as a cap increase for the new program under section 4122 of the CAA, 2023, there may be duplicative awarding of cap slots for the same program. Therefore, we are proposing to implement section 1886(h)(10)(C)(iii) of the Act by allowing rural hospitals to apply for slots to expand an existing program, but not for slots to begin a new program. We are proposing that this policy apply to both geographically rural hospitals and hospitals that have reclassified as rural under 42 CFR 412.103, since both groups of hospitals are considered rural under section 1886(h)(10)(B)(ii)(I), which we refer to as Category One hospitals. Only geographically urban hospitals that have not reclassified as rural under 42 CFR 412.103 would be permitted to apply for slots to begin a new program.

d. Distributing at Least 10 Percent of Positions to Each of the Four Categories

Section 1886(h)(10)(B)(ii) of the Act requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to each of the following categories of hospitals discussed earlier. Given our experience with distributing slots under section 126 of the CAA, 2021, we expect many hospitals will meet the qualifications of more than one category. We are proposing to collect information regarding qualification for all four categories in the distribution of slots under section 4122 of the CAA, 2023, to allow us to confirm that we have met this statutory requirement. Like the CAA, 2023 provision, section 1886(h)(9)(B)(ii) of the Act from 2021 also requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to the same four categories of hospitals. Section 126 of the CAA, 2021, makes available 1,000 residency positions and therefore, at least 100 residency positions must be distributed to hospitals qualifying in each of the four categories. In the final rule implementing section 126 of the CAA, 2021, we stated we would track progress in meeting all statutory requirements and evaluate the need to modify the distribution methodology in future rulemaking (86 FR 73441).

To date, we have completed the distribution of residency slots under rounds 1 and 2 of the section 126 distributions (refer to CMS' DGME web page for links to the round 1 and 2 awards: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme*). In tracking the statutory requirement that at least 10 percent of the aggregate number of total residency positions (100 out 1,000 slots) be distributed to hospitals qualifying in each of the four categories, we have determined that in rounds 1 and 2, only 12.76 DGME slots and 18.06 IME slots were distributed to hospitals qualifying under Category Four. For each of the other 3 categories based on the slots awarded in rounds 1 and 2, we anticipate meeting the 10 percent requirement. For example, we have determined that in rounds 1 and 2, 374.59 DGME and 375.11 IME slots were distributed to hospitals qualifying under Category Three.

As discussed in the final rule implementing section 126 of the CAA, 2021, an applicant hospital qualifies under Category Four if it participates in training residents in a program in which the residents rotate for at least 50 percent of their training time to a training site(s) physically located in a primary care or mental-health-only geographic HPSA. Specific to mental-health-only geographic HPSAs, the program must be a psychiatric or a psychiatric subspecialty program (86 FR 73430). Given that only 12.76 DGME slots and 18.06 IME slots have been distributed to hospitals qualifying under Category Four, we are proposing an amendment to our prioritization methodology for rounds 4 and 5 of section 126 of the CAA, 2021, to ensure that at least 100 residency slots are distributed to these hospitals. We are not proposing an amendment to our prioritization methodology for round 3 because the application period for round 3 runs from January 9, 2024 to March 31, 2024, prior to the date any proposals in this rule might be finalized.

Our current methodology for distributing residency slots under section 126 prioritizes slot awards based on the HPSA score associated with the program for which the hospital is applying, with higher scores receiving priority (86 FR 73434 through 73440). We are proposing that in rounds 4 and 5 of section 126 of the CAA, 2021, we will prioritize the distribution of slots to hospitals that qualify under Category Four, regardless of HPSA score. The remaining slots awarded under rounds 4 and 5 will be distributed using the existing methodology based on HPSA score (86 FR 73434 through 73440). That is, the remaining slots will be distributed to hospitals qualifying under Category One, Category Two, or Category Three, or hospitals that meet

the definitions of more than one of these categories, based on the HPSA score associated with the program for which each hospital is applying.

e. Hospital Attestation to National CLAS Standards

For section 126 of the CAA, 2021, we finalized a policy that all applicant hospitals be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) (86 FR 73441). This was to ensure that the section 126 distribution broadened the availability of quality care and services to all individuals, regardless of preferred language, cultures, and health beliefs. We stated in the final rule that the National CLAS standards are aligned with the Administration's commitment to addressing healthcare barriers, which include that residents are educated and trained in culturally and linguistically appropriate policies and practices. This continues to be the case today. Therefore, we are proposing the same requirement for section 4122 of the CAA, 2023, that we adopted for section 126 of the CAA, 2021, for the same reason. Specifically, we are proposing that in order to ensure that residents are educated and trained in culturally and linguistically appropriate policies and practices, all applicant hospitals for slots allocated under section 4122 of the CAA, 2023, would be required to attest that they meet the National CLAS Standards to ensure that the section 4122 distribution broadens the availability of quality care and services to all individuals, regardless of preferred language, cultures, and health beliefs. (For more information on the CLAS standards, please refer to *https://thinkculturalhealth.hhs.gov/*)

f. Payment of Additional FTE Residency Positions Awarded Under Section 4122 of the CAA, 2023

Section 1886(h)(10)(D) requires that CMS pay a hospital for additional positions awarded under this paragraph using the hospital's existing direct GME nonprimary care PRAs consistent with the regulations at § 413.77. We note that as specified in section 1886(h)(2)(D)(ii) of the Act, for cost reporting periods beginning on or after October 1, 1993, through September 30, 1995, each hospital's PRA for the previous cost reporting period was not updated for inflation for any FTE residents who were not either a primary care or an obstetrics and gynecology resident. As a result, hospitals with both primary care and obstetrics and gynecology residents and nonprimary care residents in FY 1994 or FY 1995 have two separate PRAs: one for primary care and obstetrics and gynecology and one for nonprimary care. Those hospitals that only trained primary care and/or obstetrics and gynecology residents and those that did not become teaching hospitals until after this 2-year period, have a single PRA for direct GME payment purposes. Therefore, we are proposing that for purposes of direct GME payments for section 4122 of the CAA, 2023, if a hospital has both a primary care and obstetrics and gynecology PRA and a nonprimary care PRA, the nonprimary care PRA will be used, and if a hospital has a single PRA, that PRA will be used. Furthermore, similar to the policy finalized for purposes of direct GME payments under section 126 of the CAA, 2021 (86 FR 73441), we are proposing that a hospital that receives additional positions under section 4122 of the CAA, 2023, would be paid for the FTE residents counted under those positions using the PRAs for which payment is made for FTE residents subject to the 1996 FTE cap. We expect to revise Worksheet E–4 to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for direct GME positions received under section 4122 of the CAA, 2023.

g. Aggregation of Additional FTE Residency Positions Awarded Under Section 4122 of the CAA, 2023

Section 1886(h)(10)(E) of the Act states that the Secretary shall permit hospitals receiving additional residency positions attributable to the increase provided under 1886(h)(10) to, beginning in the fifth year after the effective date of such increase, apply such positions to the limitation amount under paragraph (4)(F) that may be aggregated pursuant to paragraph (4)(H) among members of the same affiliated group. Therefore, we are proposing that FTE resident cap positions added under section 4122 of the CAA, 2023, may be used in a Medicare GME affiliation agreement beginning in the 5th year after the effective date of the FTE resident cap positions consistent with the regulations at 42 CFR 413.75(b) and 413.79(f). We are proposing to amend paragraph (8) at 42 CFR 413.79(f) to state that FTE resident cap slots added under section 4122 of Public Law 117–328 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

h. Conforming Regulation Amendments for 42 CFR 412.105 and 42 CFR 413.79

Section 4122 of the CAA, 2023, under subsection (b), amends section 1886(d)(5)(B) of the Act to provide for increases in FTE resident positions for IME payment purposes. Specifically, subsection (b) adds a new section 1886(d)(5)(B)(xiii) of the Act, which states that for discharges occurring on or after July 1, 2026, if additional payment is made for FTE resident positions distributed to a hospital for direct GME purposes under section 1886(h)(10) of the Act, the hospital will receive IME payments based on the additional residency positions awarded using the same IME adjustment factor used for the hospital's other FTE residents. We are proposing conforming amendments to the IME regulations at 42 CFR 412.105(f)(1)(iv)(C)(4) to specify that effective for portions of cost reporting periods beginning on or after July 1, 2026, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(q) are met. We expect to revise Worksheet E Part A to add a line on which hospitals will report the number of FTEs by which the hospital's FTE caps were increased for IME positions received under section 4122 of the CAA, 2023.

We are also proposing to amend our regulations at 42 CFR 413.79 by adding a paragraph (q) to specify that for portions of cost reporting periods beginning on or after July 1, 2026, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(10) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

i. Prohibition on Administrative and Judicial Review

Section 4122 of the CAA, 2023, under subsection (c), prohibits administrative and judicial review of actions taken under section 1886(h)(10) of the Act. Specifically, subsection (c) amends section 1886(h)(7)(E) of the Act by inserting ''paragraph (10),'' after ''paragraph (8),'' adding to the that paragraph to the list of residency distributions not subject to review. Therefore, we are proposing that the determinations and distribution of residency positions under sections 1886(d)(5)(B)(xiii) and 1886(h)(10) of the Act would be final and could not be subject to administrative or judicial review.

j. Application Process for Receiving Increases in FTE Resident Caps

All qualifying hospitals seeking increases in their FTE resident caps must submit timely applications for this distribution by March 31, 2025. The completed application must be submitted to CMS using an online application system, the Medicare Electronic Application Request Information System™ (MEARIS™). The burden associated with this information collection requirement is the time and effort necessary to review instructions and register for MEARIS™ as well as the time and effort to gather, develop and submit various documents associated with a formal request of resident position increases from teaching hospitals to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA); and as discussed in section XII.B. of this proposed rule, the burden associated with these requests will be captured under OMB control number 0938–1417 (expiration date March 31, 2025). We will submit a revised information collection estimate to OMB for approval under OMB control number 0938–1417 (expiration date March 31, 2025).

We are proposing that the following information be submitted as part of an application for the application to be considered complete:

- The name and Medicare provider number (CCN) of the hospital.
- The name of the Medicare Administrative Contractor to which the hospital submits its Medicare cost report.
- The residency program for which the hospital is applying to receive an additional position(s).
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheet E, Part A, and Worksheet E–4).
- If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 1 (New Residency Program), which of the following applies:

++ Application for accreditation of the new residency program has been submitted to the Accreditation Council for Graduate Medical Education (ACGME) (or application for approval of the new residency program has been submitted to the American Board of Medical Specialties (ABMS)) by March 31, 2025.

++ The hospital has received written correspondence from the ACGME (or ABMS) acknowledging receipt of the application for the new residency program, or other types of communication concerning the new program accreditation or approval process (such as notification of a site visit) by March 31, 2025.

- If the hospital qualifies under ''Demonstrated Likelihood'' Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

++ The hospital has received approval by March 31, 2025 from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

++ The hospital has submitted a request by March 31, 2025 for a permanent complement increase of the existing residency training program.

++ The hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME and is now seeking to fill those positions.

- Indication of the categories under section 1886(h)(10)(F)(iii) of the Act under which the hospital believes itself to qualify:

++ (I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act.

++ (II) The reference resident level of the hospital (as specified in section 1886(h)(10)(F)(iv) of the Act) is greater than the otherwise applicable resident limit.

++ (III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(10)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(10)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

++ (IV) The hospital serves an area designated as a HPSA under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

- The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA ID for that HPSA.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, stating the following:

''I hereby certify that the hospital is a Qualifying Hospital under section 1886(h)(10)(F)(iii) of the Social Security Act, and that there is a ''demonstrated likelihood'' that the hospital will fill the position(s) made available under section 1886(h)(10) of the Act within the first 5 training years beginning after the date the increase would be effective.''

''I hereby certify that (choose if applicable):

____ If my application is for a currently accredited residency program, the number of full-time equivalent (FTE) positions requested by the hospital does not exceed the number of positions for which the program is accredited.

____ If my hospital currently has unfilled positions in its residency program that have previously been approved by the ACGME, the number of FTE positions requested by the hospital does not exceed the number of previously approved unfilled residency positions.

____ If my application is for a residency training program with more than one participating site, I am only requesting the FTE amount that corresponds with the training occurring at my hospital, and any FTE training occurring at nonprovider settings consistent with 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g).''

''I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased under section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023, if awarded positions under section 1886(h)(10)(C)(ii) of the Act.''

''I hereby certify that (choose one):

____ In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA.

____ In the population HPSA the hospital is requesting that CMS use for prioritization of its application, at least 50 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the HPSA.

____ In the geographic HPSA the hospital is requesting that CMS use for prioritization of its application, at least 5 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the population of the HPSA and are physically located in the HPSA, and the program's training time at those sites plus the program's training time at Indian or Tribal facilities located outside of the HPSA is at least 50 percent of the program's training time.

____ In the population HPSA the hospital is requesting that CMS use for

prioritization of its application, at least 5 percent of the program's training time based on resident rotation schedules (or similar documentation) occurs at training sites that treat the designated underserved population of the HPSA and are physically located in the HPSA, and the program's training time at those sites plus the program's training time at Indian or Tribal facilities located outside of that HPSA is at least 50 percent of the program's training time.

____ None of the above apply.''

''I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).''

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under Federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

The completed application must be submitted to CMS using the online application system MEARIS™. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made available on the CMS Direct GME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.*

We note that if the hospital is applying using a HPSA ID, the HPSA score associated with that ID will automatically populate in the application module. In preparing their applications for additional residency positions, hospitals should refer to HRSA's Find Shortage Areas by Address (*https://data.hrsa.gov/tools/shortage-area/by-address*) to obtain the HPSA ID of the HPSA served by the program and include this ID in its application. Using this HPSA Find Shortage Areas by Address, applicants may enter the address of a training location (included on the hospital's rotation schedule or similar documentation), provided the location chosen participates in training residents in a program where at least 50 percent (5 percent if an Indian and Tribal facility is included) of the training time occurs in the HPSA. In November 2024, prior to the beginning of the application period, CMS will request HPSA ID and score information from HRSA so that recent HPSA information is available for use for the application period. CMS will only use this HPSA information, HPSA IDs and their corresponding HPSA scores, in order to review and prioritize applications. To assist hospitals in preparing for their applications, the HPSA information received from HRSA will also be posted when the MEARIS™ application module becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.*

The information will also be posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.* Click on the link on the left side of the screen associated with the appropriate final rule home page or ''Acute Inpatient—Files for Download.''

3. Proposed Modifications to the Criteria for New Residency Programs and Requests for Information

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for applying the direct GME cap in the case of medical residency training programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, this provision also applies for purposes of the IME adjustment. Accordingly, we issued regulations at §§ 413.79(e)(1) through (3) discussing the direct GME cap calculation for a hospital that begins training residents in a new medical residency training program(s) on or after January 1, 1995. The same regulations apply for purposes of the IME cap calculation at § 412.105(f)(1)(vii). CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). The calculation of both the DGME cap and IME cap for new programs is discussed in the August 31, 2012 **Federal Register** (77 FR 53416).

Section 413.79(l) defines a new medical residency training program as ''a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.''

In the August 27, 2009 **Federal Register** (74 FR 43908 through 43917), CMS clarified the definition of a ''new'' residency program and adopted supporting criteria regarding whether or not a residency program can be considered ''new'' for the purpose of determining if a hospital can receive additional direct GME and/or IME cap slots for that program. CMS adopted these criteria in part to prevent situations where a program at an existing teaching hospital would be transferred to a new teaching hospital, resulting in cap slots created for the same program at two different hospitals. To be considered a ''new'' program for which new cap slots would be created, a previously non-teaching hospital would have to ensure that the program meets three primary criteria (74 FR 43912):

- The residents are new, and
- The program director is new, and
- The teaching staff are new.

Over the years, we have received questions regarding the application of these criteria, such as whether CMS would still consider a program to be new for cap adjustment purposes if the three criteria were partially, but not fully, met. We have answered such questions by stating that, generally, a residency program's newness would not be compromised as long as the ''overwhelming majority'' of the residents or staff are not coming from previously existing programs in that same specialty.

The question of what constitutes a ''new'' program for purposes of receiving additional Medicare-funded GME slots has taken on increasing significance in light of the ability of urban hospitals to reclassify as rural under 42 CFR 412.103 for IME purposes, and thus receive additional IME cap slots for any new program started. To continue to ensure that newly funded cap slots are created appropriately, we ultimately would like to establish in rulemaking additional criteria for determining program newness. However, we are not yet certain about some of the criteria that should be proposed, and so we are soliciting comments to gain additional clarity on best practices in these areas. Accordingly, we discuss the items we are proposing and the items on which we are soliciting public input through a Request for Information (RFI).

a. Newness of Residents

Generally, when a hospital is creating a new residency program, it recruits individuals that have recently graduated from medical school, have no previous residency training experience, and

would be entering the program as first year (PGY1) residents. However, new programs sometimes receive inquiries from applicants that have training experience already, but for a variety of reasons need to transfer to another program. If the program that such a resident wishes to join is still within the 5-year cap building period, then, consistent with the criteria adopted in the August 27, 2009 final rule, the program director of this ''new'' program should be judicious with regard to accepting residents who have received previous training in the same specialty. In order to maintain the classification as a ''new'' residency program, the ''overwhelming majority'' of residents in the program must be new. We believe it would be useful for the provider community to have a concrete standard to refer to in determining whether the ''overwhelming majority'' of residents in a program are in fact new. Therefore, we propose that, in order for a residency program to be considered new, at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. For example, if there were 50 trainees (not FTEs) entering the program over the course of the 5-year cap building period, then at least 45 of the trainees (90 percent of 50) must enter the program as brand new first year residents in that particular specialty. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, we propose that this would render the program ineligible for new cap slots. (Note—we would apply standard rounding when 90 percent of a number does not equal a whole number, rounding down to the nearest whole number when the remainder is less than 0.5, and rounding up to the nearest whole number when the remainder is 0.5 or above. For example, if there were 48 trainees (not FTEs) entering the program over the course of the 5-year cap building period, then at least 43 of the trainees (90 percent of 48 = 43.2, which rounds down to 43) must enter the program as brand new first year residents in that particular specialty. If there were 45 trainees (not FTEs) entering the program, then at least 41 of the trainees (90 percent of 45 = 40.5, which rounds up to 41) must enter the program as brand new first year residents in that particular specialty.)

For example, if a new program is in internal medicine, then at least 90 percent of the entering residents must *not* have previously enrolled and trained in an internal medicine program. If a resident was formally enrolled in an internal medicine program (either preliminary or categorical), even if that resident switched programs during their first year of training, then we would consider that resident to have had previous training in that same specialty. Conversely, if an individual was a resident in a specialty *other* than internal medicine, and that resident switched into the new internal medicine program and began training in the new internal medicine program as a PGY1, then that resident would not be considered to have had previous training in the same specialty, and would be counted as a brand new resident. (Note, we are distinguishing between a resident that is *not* enrolled in an internal medicine program but may have done a rotation in internal medicine as part of the requirements for a different specialty, from a resident that actually was enrolled and participated in an internal medicine program, consistent with the definition of ''*resident*'' at 42 CFR 413.75(b). In this example, we are generally focusing on individuals who were accepted, enrolled, and participated in internal medicine; we are generally not concerned with an individual that was enrolled, accepted, and participated in a program other than internal medicine but did a rotation in internal medicine.) We propose that the proportion of brand new residents in a residency program would be determined by the MAC based on all the individuals (not FTEs) that enter the program as a whole at any point during the 5-year cap building period, after the end of the 5 years.

We are proposing a threshold of 90 percent for new residents as that is generally consistent with the concept of an ''overwhelming majority,'' and because we have precedent for such a threshold in the regulations for section 5506 of the Affordable Care Act, which State that a hospital is considered to have taken over an ''entire'' program from a closed hospital if it can demonstrate that it took in 90 percent or more of the FTE residents in that program. Accordingly, for a program to be considered ''new'' for the purpose of determining if a hospital can receive additional direct GME and/or IME cap slots for that program, we propose that at least 90 percent of the individual resident trainees (not FTEs) in the program as a whole must not have had previous training in the same specialty as the new program. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, we propose that this would render the program as a whole (but not the entire hospital or its other new programs, if applicable) ineligible for new cap slots.

In addition, we understand that there may be certain challenges that are unique to small or rural-based programs in developing new residencies, and that meeting a proposed threshold of 90 percent of resident trainees with no previous training experience in the specialty may be more difficult for those programs. Accordingly, we are soliciting comments on what should be considered a ''small'' program and what percentage threshold or other approach regarding new resident trainees should be applied to these programs. We solicit comment on defining a small residency program as a program accredited for 16 or fewer resident positions, because 16 positions would encompass the minimum number of resident positions required for accredited programs in certain specialties, such as primary care and general surgery, that have historically experienced physician shortages, and therefore have been prioritized by Congress and CMS for receipt of slots under sections 5503 and 5506 of the Affordable Care Act.

b. Newness of Faculty and Program Director—RFI (Request for Information)

Regarding the selection of teaching staff and a program director, we understand that it would be reasonable for a new program to wish to hire some staff that already have experience teaching residents and operating a program. Therefore, to accommodate the hiring of some experienced staff, we believe that the percentage of faculty with no previous experience teaching in a program in the same specialty should probably be less than 90 percent, but we are uncertain what the appropriate threshold should be. At one extreme, we can envision a scenario where recruitment of most or all of the experienced staff from a particular existing program may even result in the disintegration of and possible closure of that existing program. Such a situation could be chaotic to that hospital and leave residents scrambling for alternative sites to complete their training. Consequently, we do believe there should be some threshold for the relative proportion of non-experienced and experienced staff at a new residency program, and we are requesting information from commenters regarding what a reasonable threshold might be. We also are seeking comment on the variables involved in examining the

newness of teaching staff. We note that the ACGME defines ''Core Faculty'' [156] in its *Glossary of Terms* as physician teachers that devote at least 15 hours per week to a residency program, or 10 hours per week to a fellowship. However, in addition to other minimum hours for staff, there may be other types of faculty or staff that CMS should consider to be involved in a program. We are therefore soliciting information from commenters regarding whether any threshold for determining the newness of teaching staff for a new program should consider only the ACGME's definition of ''Core Faculty'', or count non-core faculty as well.

While we are uncertain what percentage the threshold for experienced faculty should be, we are suggesting a threshold for commenters to consider. We suggest that up to 50 percent of the teaching staff in a new program may come from a previously existing program in the same specialty, but if so, each of those staff members should come from *different* previously existing programs. For example, if there are 6 teaching staff total, then at least 3 must have no previous experience teaching in the same specialty, while up to 3 may come from previously existing programs in the same specialty; however, each of the 3 experienced faculty would have to come from a *different* previously existing program. That is, one may come from Hospital A's existing program, another could come from Hospital B's existing program, and a third could come from Hospital C's existing program; but no more than one could come from any of Hospital A, Hospital B, or Hospital C. If two were to come from Hospital A, we suggest that would not be permissible.

We have also been asked whether it would make a difference if a faculty member had previous teaching experience, but a certain amount of time has passed since they taught in a program in the same specialty (for example, because they accepted a non-teaching job in a different hospital, or the program where they previously taught has ceased to operate). As mentioned previously, we would want to avoid loss of most or all of an existing program's experienced faculty. However, we believe this concern might be mitigated if a faculty member has not been associated with an existing program for a certain amount of time, or if the program in question has closed.

In the August 27, 2009 **Federal Register**, we discussed the specific scenario in which a hospital discontinued one of its previously existing residency programs, and then established a program in the same specialty at some time in the future:

''[I]f a hospital wishes to begin training residents in a particular program in which it trained residents in the past, but the program *has not trained residents for the past 10 years, the program could be subsequently considered a new program.* We believe that a program that is closed for *several years* and then reopens is separate and distinct from the previous program, and would likely not involve any residents that had trained in the previous program, even though, as the commenter indicated, the directors and teaching staff may be the same. (However, we note that it may be necessary to determine whether the program director and the teaching staff have been training [dental] residents during the past 10 years at another training site in order to determine whether the program at the hospital that is beginning to train residents after a 10-year hiatus is truly a new program)'' (74 FR 43916, emphasis added).

We continue to believe that if a hospital wishes to begin training residents in a particular program in which it trained residents in the past, but the program has not trained residents for the past 10 years, the program could be subsequently considered a new program. More generally, we believe that, in determining whether the presence of a faculty member might jeopardize the newness of a new residency program, it may make sense to consider whether a certain amount of time has passed since that faculty member last taught in another program in the same specialty. We are therefore soliciting comments on whether 10 years, or some other amount of time, would be an appropriate period during which a faculty member should not have had experience teaching in a program in the same specialty. For example, it might make sense to consider whether a staff member taught in another program in the same specialty at any point during the 5 years prior to their employment in the ''new'' program, as 5 years is the time associated with building a new FTE cap, but not to consider teaching experience from more than 5 years ago.

In addition, since we understand that a new teaching hospital may also want to recruit an experienced program director, we are soliciting comments on whether it would make sense to define a similar period of time (for example, 10 years or 5 years) during which an individual must not have been employed as the program director in a program in the same specialty. In formulating suggestions, commenters may want to consider whether the suggested period of time (for example, 10 years or 5 years) aligns or conflicts with the ACGME common program requirements, which State that program director qualifications ''must include specialty expertise and at least three years of documented educational and/or administrative experience, or qualifications acceptable to the Review Committee'' (*https://www.acgme.org/globalassets/pfassets/programrequirements/cprresidency_2023.pdf*).

Finally, we understand that there may be unique issues that small or rural residencies face in recruiting qualified program directors and faculty to ensure success during the early years of the residency. In small programs, when there may only be 2 or 3 core faculty members, flexibility may be necessary in the proportions of new and experienced teaching staff. As stated previously, we are soliciting comments on what should be considered a ''small'' program (for example, programs accredited for 16 or fewer positions), and what staff threshold or other approach should be applied to small, which may include rural, programs.

To summarize, we are soliciting comments on the following points regarding the determination of whether the faculty and program director are new:

- What is a reasonable threshold for the relative proportions of experienced and new teaching staff? Should there be different thresholds for small, which may include rural, residency programs?
- Should a threshold for determining newness of teaching staff for a new program consider only Core Faculty, or non-core faculty (or key non-faculty staff) as well?
- We seek feedback on our suggestion that 50 percent of the teaching staff may come from a previously existing program in the same specialty, but if so, the 50 percent should comprise staff that each came from *different* previously existing programs in the specialty.
- In considering whether the presence of a faculty member might jeopardize the newness of a new program, would it be reasonable to consider whether 10 years or 5 years, or some other amount of time, has passed

[156] Core Faculty: All physician faculty members who have a significant role in the education of residents/fellows and who have documented qualifications to instruct and supervise. Core faculty members devote at least 15 hours per week to resident, or 10 hours per week to fellow, education and administration. All core faculty members should evaluate the competency domains, work closely with and support the program director, assist in developing and implementing evaluation systems, and teach and advise residents/fellows. (*https://www.acgme.org/globalassets/pdfs/ab_acgmeglossary.pdf*).

during which that faculty member has not had experience teaching in a program in the same specialty?

- Would it make sense to define a similar period of time (for example, 10 years or 5 years) during which an individual must not have been employed as the program director in a program in the same specialty? Should there be a different criterion for small, which may include rural, residency programs?

c. Commingling of Residents in a New and an Existing Program—RFI

We have learned that it is not uncommon for residents in separately accredited programs, but in the same specialty, to meet and share some clinical and didactic training experiences, which for the purpose of this discussion we refer to as ''commingling.'' For example, residents in two separately accredited anesthesiology programs may receive training simultaneously in a certain niche surgical competency, and may collaborate in certain shared scholarly activities required for completion of the anesthesiology residency. This is an issue different from the newness of residents, as the residents in this case are separately matched into distinct programs, yet have certain current training experiences in common. We believe this cooperative approach may be reasonable from an educational perspective, yet when taken to an extreme, may result in the inappropriate creation of new cap slots for a program that looks more like an expansion of an existing program rather than the formation of a truly new program. As an extreme example, we consider a hypothetical case in which a ''new'' program and an existing program share 100% of resident rotations, using the same faculty, and rotating simultaneously to the same locations. In this case, the ''new'' program would be just a ''carbon copy'' of the existing one. On the other hand, even a small percentage of shared rotations can be concerning, as shown under the following scenario:

Assume New Teaching Hospital (NTH) A starts a new Family Medicine residency program. Residents in the new program spend 90 percent of their time at NTH Hospital A, and 10 percent at Existing Teaching Hospital (ETH) B. ETH B has reclassified as rural under 42 CFR 412.103, and is eligible for an IME cap adjustment for any portion of participation in the new program. NTH A hires a brand new program director and brand new faculty, and all the residents are new, so the newness criteria we adopted in the August 27, 2009 **Federal Register** are satisfied. However, during the 10 percent of total time they spend at ETH B, residents in the program share their rotations with residents in ETH B's existing Family Medicine program.

In this case, commingling accounts for only 10 percent of total program time, but for 100 percent of the time at ETH B's existing Family Medicine program. Under current regulations at 42 CFR 413.79(e)(1)(vi), ETH B would receive a one-tenth share of the overall IME cap increase, even though that 10 percent of resident time is functionally an expansion of its existing Family Medicine program. We are soliciting comments on whether and what amount, if any, of commingling is appropriate among residents in an existing program and residents in a program where training is occurring at a hospital that may be eligible for an FTE cap increase for training residents in a new program.

d. One Hospital Sponsoring Two Programs in the Same Specialty—RFI

We have been asked whether it is permissible for one hospital to operate two programs in the same specialty. We have heard this commonly occurs in states with more sparsely populated areas, where there is often one dominant academic medical center/sponsor of residency programs in the state, and that sponsor creates more than one program in a specialty to provide access to care in different areas of the state. We have answered this question by saying that if each program in fact has separate program directors, and separate staff, and separately matched residents, then it is permissible for one hospital to sponsor two programs in the same specialty.

However, we are taking the opportunity to solicit comments on why hospitals might want to train residents in separately accredited programs, but in the same specialty, and the degree to which this happens in general, in both sparsely populated and more densely populated areas. In conjunction with our solicitation of previous comments regarding commingling of residents in different programs in the same specialty, and our concerns regarding new FTE caps created for programs that may not truly be new at hospitals with an urban-to-rural reclassification, we are interested in hearing from commenters regarding the reasons why hospitals may sponsor more than one program in the same specialty, including but not limited to Rural Track Programs, and the degree to which commingling may occur in these programs.

4. Technical Fixes to the DGME Regulations

In the course of our ongoing implementation of policies concerning payment for graduate medical education, we have become aware of the existence of several technical errors in the direct GME regulations at 42 CFR 413.75 through 413.83. We therefore propose to correct these technical errors, as discussed later.

a. Correction of Cross-References to § 413.79(f)(7)

In the FY 2010 IPPS final rule (74 FR 43918 and 44001, August 27, 2009), we amended 42 CFR 413.79(f) by adding a new paragraph (f)(6) and redesignating existing paragraph (f)(6) as paragraph (f)(7). The new § 413.79(f)(6) sets forth requirements for participation in a Medicare GME affiliated group by a hospital that is new after July 1 and begins training residents for the first time after the July 1 start date of an academic year, while the redesignated § 413.79(f)(7) contains the regulations pertaining to emergency Medicare GME affiliated groups.

We have discovered that, after redesignating the former § 413.79(f)(6) as § 413.79(f)(7), we inadvertently did not update the cross-references to this paragraph at §§ 413.75(b) and 413.78. Accordingly, in this proposed rule, we are proposing to revise the language of the definition of ''Emergency Medicare GME affiliated group'' under § 413.75(b), as well as the language at §§ 413.78(e)(3)(iii) and (f)(3)(iii), by correcting the cross-references to read ''§ 413.79(f)(7).''

b. Removal of Obsolete Regulations Under § 413.79(d)(6)

Under 42 CFR 413.79(h), a hospital may receive a temporary adjustment to its FTE cap to reflect displaced residents added as a result of the closure of another hospital or residency training program. Furthermore, under § 413.79(d)(6)(i) (previously § 413.79(d)(6)), displaced residents counted under a temporary cap adjustment are added to the receiving hospital's FTE count after application of the three-year rolling average for the duration of the time that the displaced residents are training at the receiving hospital.

In the November 24, 2010 final rule (75 FR 72212 through 72238), we implemented the provisions of section 5506 of the Affordable Care Act, which directs the Secretary to redistribute Medicare GME residency slots from teaching hospitals that close after March 23, 2008. A hospital that had previously

accepted residents displaced by a teaching hospital closure and received a temporary cap adjustment for training those residents under § 413.79(h) may subsequently apply for a permanent cap increase under section 5506.

As part of the implementation of section 5506, we finalized several ranking criteria to prioritize applications, and specified the dates on which awards would become effective for hospitals that apply under each of those criteria. In particular, we finalized Ranking Criteria One and Three, which describe applicant hospitals that take over, respectively, an entire residency program(s) or part of a residency program(s) from the closed hospital. Consistent with the policy finalized in the November 24, 2010 final rule, a permanent cap increase awarded under Ranking Criterion One or Three would generally override any temporary cap adjustment that the applying hospital may have received under § 413.79(h), with the result that those resident slots would immediately become subject to the three-year rolling average calculation (75 FR 72224).

We also stated, however, that we believed it would still be appropriate to allow a hospital that ultimately would qualify to receive slots permanently under any of the ranking criteria and that took in displaced residents to receive temporary cap adjustments and, in a limited manner, an exemption from the three-year rolling average. Therefore, we finalized a policy that, in the first cost reporting period in which the applying hospital takes in displaced residents and the hospital closure occurs, the applying hospital could receive a temporary cap adjustment and an exemption from the rolling average for the displaced residents. Then, effective beginning with the cost reporting period following the one in which the hospital closure occurred, the applying hospital's permanent cap increase would take effect, and there would be no exemption from the rolling average (75 FR 72225 and 72263).

Therefore, we amended § 413.79(d) by redesignating the existing paragraph (d)(6) as (d)(6)(i) and by adding new (d)(6)(ii), which states stated that if a hospital received a permanent increase in its FTE resident cap under § 413.79(o)(1) due to redistribution of slots from a closed hospital, the displaced FTE residents that the hospital received would be added to the FTE count after applying the averaging rules only in the first cost reporting period in which the receiving hospital trained the displaced FTE residents. In subsequent cost reporting periods, the displaced FTE residents would be included in the receiving hospital's rolling average calculation.

Subsequently, in the FY 2013 IPPS final rule (77 FR 53437 through 53443, August 31, 2012), we finalized revisions to our policy concerning the effective dates of section 5506 cap increases awarded under the various ranking criteria. In particular, we finalized a policy that slots awarded under Ranking Criteria One and Three become effective seamlessly with the expiration of temporary cap adjustments under § 413.79(h) (that is, on the day after the graduation date(s) of the displaced residents). As stated in that final rule, under this revised policy, permanent cap increases under section 5506 would no longer ''replace'' temporary cap adjustments under § 413.79(h), and exemptions from the three-year rolling average would no longer be suspended as a consequence of the receipt of permanent slots (77 FR 53441).

Under the policy finalized in the FY 2013 IPPS final rule, there is no longer any need for the regulation at § 413.79(d)(6)(ii), which would apply in the situation where a permanent cap increase under section 5506 would otherwise have overridden a temporary cap adjustment for displaced residents under § 413.79(h). Instead, our policy is that displaced residents are excluded from the receiving hospital's rolling average calculation for the duration of the time that they are training at the receiving hospital, as specified at § 413.79(6)(i). However, we have discovered that we neglected to make the appropriate revisions to the regulations text to reflect our current policy.

Accordingly, we are proposing to amend § 413.79(d)(6) by removing the no longer applicable paragraph (d)(6)(ii), and by redesignating existing (d)(6)(i) as (d)(6).

c. Correction of Typographical Errors at § 413.79(k)(2)(i)

In the final rule published on December 27, 2021, as part of the implementation of section 127 of the CAA, 2021 (Pub. L. 116–260), we finalized various changes throughout the regulations text at 42 CFR 413.79(k), ''Residents training in rural track programs'' (86 FR 73445 through 73457 and 73514 through 73515). We have discovered that the final sentence of § 413.79(k)(2)(i), as amended in that rule, incorrectly states, ''For Rural Track Programs prior to the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence . . .''

The beginning of the quoted sentence should instead refer to ''cost reporting periods beginning on or after October 1, 2022,'' and should otherwise be analogous to the similar text that appears at § 413.79(k)(1)(i). Accordingly, we are proposing to revise § 413.79(k)(2)(i) to read as follows: ''For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital and, subject to the requirements under § 413.78(g), at the rural nonprovider site(s).''

5. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the full-time equivalent (FTE) resident caps in teaching hospitals that closed on or after a date that is 2 years before the date of enactment (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain additional modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that

close after August 3, 2010 (75 FR 72215).

b. Notice of Closure of McLaren St. Luke's Hospital Located in Maumee, OH, and the Application Process—Round 21

CMS has learned of the closure of McLaren St. Luke's Hospital Located in Maumee, OH (CCN 360090). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 21st round (''Round 21'') of the application and selection process. The table in this section of this rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 21 application process under section 5506 of the Affordable Care Act.

TABLE V.F.-01: MCLAREN ST. LUKE'S HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap	Direct GME FTE Resident Cap
360090	McLaren St. Luke's Hospital	Maumee, OH	45780	May 9, 2023	14.93	14.93

c. Notice of Closure of South City Hospital Located in St. Louis, MO, and the Application Process—Round 22

CMS has learned of the closure of South City Hospital, located in St. Louis, MO (CCN 260210). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round (''Round 22'') of the application and selection process. This round will be the 22nd round (''Round 22'') of the application and selection process. The table in this section of this rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 22 application process under section 5506 of the Affordable Care Act.

TABLE V.F.-02: SOUTH CITY HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including+/- Sec. 5503 of the Affordable Care Act [1] adjustments)	Direct GME FTE Resident Cap
260210	South City Hospital	St. Louis, MO	41180	November 18, 2023	73.00 – 5.46 sec. 5503 reduction = 67.54 [2]	74.00

[1] Section 5503 of the Affordable Care Act of 2010, Pub. L. 111–148 and Pub. L. 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.

[2] South City Hospital's 1996 IME FTE resident cap is 73.00. Under section 5503 of the Affordable Care Act, the hospital received a reduction of 5.46 to its IME FTE resident cap: 73.00 – 5.46 = 67.54.

d. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the previously noted hospitals' FTE resident caps must submit applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), with application submissions for Round 21 and Round 22 due no later than July 9, 2024. The Section 5506 application can be accessed at: *https://mearis.cms.gov/public/home.*

CMS will only accept Round 21 and Round 22 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the ''Resources'' section for guidance regarding the application submission process at: *https://mearis.cms.gov/public/resources.*
- Technical support is available under ''Useful Links'' at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources.*

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme.* Hospitals should access this website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

6. Reminder of Core-Based Statistical Area (CBSA) Changes and Application to GME Policies

In section III.B. of the preamble of this proposed rule, we discuss the proposed changes to the most recent OMB standards for delineating statistical areas announced in the July 21, 2023 OMB Bulletin No. 23–01. We refer to these statistical areas as Core-Based Statistical Areas (CBSAs). As a result of the new OMB delineations, some teaching hospitals may be redesignated

from being located in a rural CBSA to an urban CBSA, or from being located in an urban CBSA to a rural CBSA. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111, August 22, 2014), we last discussed the effects of the CBSA changes on IME and DGME payment policy, as at that time, we implemented the changes to the statistical areas resulting from the February 28, 2013, OMB Bulletin No. 13–01. We refer readers to the FY 2015 IPPS/LTCH PPS final rule to learn more about CMS' policies regarding changes to the CBSAs and how IME and DGME payments are impacted. We emphasize that we are not currently proposing any additional policies as a result of the latest CBSA changes; we are merely providing a reference for readers that may have questions about our existing policies. As a general overview, the FY 2015 IPPS/LTCH PPS final rule discusses the effect on the FTE caps of a hospital that was located in a rural CBSA, either at the time that it started training residents in a new residency program, or was located in a rural area when it received accreditation for a new program, but either prior to actually starting the program or during the 5-year cap building period, the CBSA in which the hospital was located became an urban CBSA (79 FR 50111 through 50113). We also discussed what happens to a rural training track when a rural hospital that is participating as the rural site is redesignated as urban, either during the period when the rural track is being established, or after it has been established (79 FR 50113). (Note that under 42 CFR 413.75(b) and 413.79(k), we now refer to rural training tracks as Rural Training Programs (RTPs)). We provided for a transition period, wherein either the redesignated urban hospital must reclassify as rural under § 412.103 for purposes of IME payment only (in addition, this reclassification option only applies to IPPS hospitals (or CAHs under 42 CFR 412.103(a)(6)), not other nonprovider sites), or the ''original'' urban hospital must have found a new site in a geographically rural area that will serve as the rural site for purposes of the rural track in order for the ''original'' urban hospital to receive payment under § 413.79(k)(1) or (k)(2). Also see DGME regulations at 42 CFR 413.79(c)(6), 42 CFR 413.79(k)(7), and for IME, at 42 CFR 412.105(f)(1)(iv)(D).

G. Reasonable Cost Payment for Nursing and Allied Health Education Programs (§§ 413.85 and 413.87)

a. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or are recognized by a national accrediting body. The costs of these programs are excluded from the definition of ''inpatient hospital operating costs'' and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis). Existing regulations on NAH education program costs are located at 42 CFR 413.85. The most recent substantive rulemakings on these regulations were in the January 12, 2001 final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434).

b. Medicare Advantage Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now called Medicare Advantage (MA)) enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs may receive additional payments to account for MA enrollees. Section 541 of the BBRA limits total spending under the provision to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool''.) Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for Medicare+Choice utilization are reduced to the extent that these additional payments are made for nursing and allied health education programs. This provision was effective for portions of cost reporting periods occurring in a CY, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for MA nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital's specific MA utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital's MA utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year, beginning with CY 2001.

The regulations at 42 CFR 413.87 codified both statutory provisions. We first implemented the BBRA NAH MA provision in the August 1, 2000 IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039), and subsequently implemented the BIPA provision in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910). In those rules, we outlined the qualifying conditions for a hospital to receive the NAH MA payment, how we would calculate the NAH MA payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same variables, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH pass-through payment/ Hospital Part A Inpatient Days) * Hospital MA Inpatient Days)/ ((National NAH pass-through payment/National Part A Inpatient Days) * National MA Inpatient Days)) * Current Year Payment Pool.

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary would estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection 1886(h)(3)(D)

of the Act to total direct GME payments estimated for the same portions of periods under section 1886(h)(3) of the Act.

Accordingly, we stated in the August 1, 2000 IFC (65 FR 47038) that each year, we would determine and publish in a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year 2 years prior to the current calendar year. We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year (65 FR 47038).

To calculate the pool, in accordance with section 1886(l) of the Act, we stated that we would ''estimate'' a total amount for each calendar year, not to exceed $60 million (65 FR 47038). To calculate the proportional reduction to Medicare+Choice (now MA) direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME payments are based on the best available cost report data from the HCRIS (for example, for calendar year 2000, the projections are based on the best available cost report data from HCRIS 1998), and these payment amounts are increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI–U) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000 IFC, we described our policy regarding the timing and source of the national data components for the NAH MA add-on payment and the percent reduction to the direct GME MA payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000 IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000 IFC states that we would publish the NAH MA rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and CY 2021, we proposed and finalized the NAH MA add-on rates in the FY 2023 IPPS/LTCH PPS proposed and final rules. We stated that for CYs 2022 and after, we would similarly propose and finalize their respective NAH MA rates and direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073, August 10, 2022).

In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing the rates for CY 2023. Consistent with the use of HCRIS data for past calendar years, we are proposing to use data from cost reports ending in FY 2021 HCRIS (the fiscal year that is 2 years prior to CY 2023) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days.

For this proposed rule, we accessed the FY 2021 HCRIS data from the fourth quarterly HCRIS update of 2023. However, to calculate the ''pool''' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar year, which in this proposed rule is CY 2023, based on the ''best available cost report data from the HCRIS'' (65 FR 47038). Next, consistent with the method we described previously from the August 1, 2000 IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index (CPI–U) increases for Part A direct GME). For CY 2023, the direct GME projections are based on the fourth quarterly update of CY 2021 HCRIS, adjusted for the CPI–U and for increasing MA enrollment.

For CY 2023, the proposed national rates and percentages, and their data sources, are set forth in this table. We intend to update these numbers in the FY 2025 final rule based on the latest available cost report data.

CY 2023 NAH MA Rates	CY 2023	SOURCE
NAH Pass-Through	$281,138,358	Cost reports ending in FY 2021 HCRIS
Part A Inpatient Days	70,195,536	Cost reports ending in FY 2021HCRIS
MA Inpatient Days	13,699,344	Cost reports ending in FY 2021HCRIS
Part A Direct GME	$2,925,379,833	CY 2021 HCRIS + CPI-U + MA enrollment
MA Direct GME	$2,198,792,484	CY 2021 HCRIS + CPI-U + MA enrollment
Pool (not to exceed $60 million)	$60,000,000	((MA DGME /Part A DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	2.73%	Pool/MA direct GME

H. Proposed Payment Adjustment for Certain Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of

immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when, among other criteria, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (21 CFR 312.305).[157]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial (85 FR 58844).

For FY 2025, we are proposing to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that would group to MS–DRG 018, as calculated using the same methodology, as modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59062), that we are proposing to use to adjust the case count for purposes of the relative weight calculations, as described in section II.D. of the preamble of this proposed rule.

As discussed in the FY 2024 IPPS/LTCH PPS final rule, the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2023 MedPAR data and for subsequent years, this field identifies whether or not the claim includes condition code 90. The MedPAR files now also include information for claims with the payer-only condition code ''ZC'', which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*). We refer the readers to section II.D. of the preamble of this proposed rule for further discussion of our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 and our methodology used to adjust the case count for purposes of the relative weight calculations, as modified in the FY 2024 IPPS/LTCH PPS final rule.

Using the same methodology that we are proposing to use to adjust the case count for purposes of the relative weight calculations, we are proposing to calculate the adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases as follows:

- Calculate the average cost for cases assigned to MS–DRG 018 that either (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'' or (b) contain condition code ''90''.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

We refer the readers to section II.D. of the preamble of this proposed rule for further discussion of our methodology.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for this proposed rule we propose to calculate this adjustor based on the December 2023 update of the FY 2023 MedPAR file for purposes of establishing the FY 2025 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), we propose to multiply the FY 2025 relative weight for MS–DRG 018 by a proposed adjustor of 0.34 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We also propose to update the value of the adjustor based on more recent data for the final rule.

I. Proposed Changes to the Calculation of the IPPS Add-On Payment for Certain End-Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under existing regulations at § 412.104, we provide an additional payment to a hospital for inpatient services provided to certain Medicare beneficiaries with ESRD who receive a dialysis treatment during a hospital stay, if the hospital's ESRD Medicare beneficiary discharges, excluding discharges classified into the MS–DRGs listed at § 412.104(a), where the beneficiary received dialysis services during the inpatient stay, are 10 percent or more of its total Medicare discharges. The additional payment (referred to as the ESRD add-on payment) is intended to lessen the impact of the added costs for hospitals that deliver inpatient dialysis services to a high concentration of ESRD Medicare beneficiaries (76 FR 51692). The additional payment is based on the average length of stay for ESRD beneficiaries in the facility times a factor based on the average direct cost of furnishing dialysis services during a

[157] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

usual beneficiary stay (49 FR 34747). The payment to a hospital equals the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to 1 week, times the estimated weekly cost of dialysis multiplied by the number of ESRD beneficiary discharges not excluded under § 412.104(a). The average direct cost of dialysis was determined from data obtained in connection with establishing the composite rate reimbursement for outpatient maintenance dialysis (49 FR 34747).

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (74 FR 49927). The ESRD PPS replaced the basic case-mix adjusted composite rate payment system and the payment methodologies for separately billable outpatient renal dialysis items and services. Payment under Medicare Part B for outpatient renal dialysis services has been based entirely on the ESRD PPS since January 1, 2014 (78 FR 72160). The ESRD PPS pays ESRD facilities a case-mix-adjusted, bundled payment, which includes former composite rate services and ESRD-related drugs, laboratory services, and medical equipment and supplies (80 FR 68973). The ESRD PPS base rate is designed to reflect the average cost per-treatment of providing renal dialysis services.[158] The per treatment payment amount (that is, the ESRD PPS base rate, subject to applicable adjustments) [159] is typically applied to a regimen of three hemodialysis treatments per week. CMS updates the ESRD PPS base rate annually. We refer readers to the August 12, 2010, ESRD PPS final rule (75 FR 49030 through 49214) for additional details on the establishment of the ESRD PPS, including a discussion of the transition from the basic case-mix adjusted composite rate payment system to the ESRD PPS.

As described previously, under current regulations the ESRD add-on payment is based on the average direct cost of furnishing dialysis services determined from data obtained in connection with establishing the composite rate. Under the current regulations, the average cost of dialysis is reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed. The last time CMS updated the composite rate was in the CY 2013 ESRD PPS final rule (77 FR 67454), as this was the final year in which payments to ESRD facilities were based on a blend of the composite rate and the ESRD PPS. In light of the time that has passed since the last update to the composite rate, we are proposing to change the methodology used to calculate the ESRD add-on payment under current regulations to the ESRD PPS base rate used under the ESRD PPS. In addition, since the renal dialysis services reflected in the ESRD PPS base rate do not include those services that are not essential for the delivery of maintenance dialysis (see § 413.171), using the ESRD PPS base rate to calculate the ESRD add-on payment would maintain consistency with the current calculation, which is based on the average costs determined to be directly related to the renal dialysis service, as determined from the composite rate.

As described previously, under § 412.104(b)(1), the ESRD add-on payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital. We are proposing that effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis would be calculated as the applicable ESRD PPS base rate (as defined in 42 CFR 413.171) multiplied by three, which represents the typical number of dialysis sessions per week. The ESRD PPS base rate is applicable for renal dialysis services furnished during the calendar year (CY) (that is, effective January 1 through December 31 each year) and updated annually (see § 413.196). Under this proposal, the annual CY ESRD PPS base rate (as published in the applicable CY ESRD PPS final rule or subsequent corrections, as applicable) multiplied by three would be used to calculate the ESRD add-on payment for hospital cost reporting periods that begin during the Federal FY for the same year. For example, the CY 2025 ESRD PPS base rate would be used for all cost reports beginning during Federal FY 2025 (that is, for cost reporting periods starting on or after October 1, 2024, through September 30, 2025). The table that follows illustrates the applicable CY ESRD PPS base rate that would be used to determine the add-on amount for eligible discharges during the hospital's cost reporting periods beginning on or after October 1, 2024 (FY 2025) and on or after October 1, 2025 (FY 2026) under this proposed methodology.

We note that use of the applicable CY ESRD PPS base rate to determine the add-on payment amount for the hospital's discharges occurring during the entire cost reporting period based on the cost report's begin date would be consistent with the determination of eligibility for the ESRD add-on payment, which occurs at cost report settlement and is based on the discharges that occur during that cost reporting period.

PROPOSED FY COST REPORT PERIOD ALIGNMENT WITH CY ESRD PPS BASE RATE FOR FYs 2025 and 2026

FY IPPS Hospital Cost Report Period	Applicable ESRD PPS Base Rate
Cost reports beginning on or after October 1, 2024 through September 30, 2025 (FY 2025)	CY 2025 (January 1, 2025 – December 31, 2025)
Cost reports beginning on or after October 1, 2025 through September 30, 2026 (FY 2026)	CY 2026 (January 1, 2026 – December 31, 2026)

[158] 42 CFR 413.215(a) and 413.220.

[159] § 413.230.

Under this proposal, the payment to a hospital would continue to be calculated as the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to 1 week, multiplied by the estimated weekly cost of dialysis multiplied by the number of applicable ESRD beneficiary discharges. Specifically, for cost reporting periods beginning on or after October 1, 2024, the proposed payment to a hospital would equal the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to 1 week, multiplied by the estimated weekly cost of dialysis (calculated as the applicable ESRD PPS base rate (as defined in 42 CFR 413.171), multiplied by 3) multiplied by the number of ESRD beneficiary discharges except for those excluded under § 412.104(a).

We are proposing to revise the regulations under 42 CFR 412.104(b) to reflect this proposed change to the calculation of the payment amount for cost reporting periods beginning on or after October 1, 2024. We are proposing to revise § 412.104(b)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis is calculated as 3 dialysis sessions per week multiplied by the applicable ESRD PPS base rate (as defined in 42 CFR 413.171) that corresponds with the fiscal year in which the cost reporting period begins. For example, the CY 2025 ESRD PPS base rate (multiplied by 3 to determine the estimated weekly cost of dialysis, as described previously) would apply for all hospital cost reporting periods beginning during FY 2025 (that is, for cost reporting periods beginning on or after October 1, 2024, through September 30, 2025). We are also proposing to make conforming changes to § 412.104(b)(3) and § 412.104(b)(4) to reflect the proposed change in methodology for calculating the ESRD add-on payment amount for cost reporting periods beginning on or after October 1, 2024.

J. Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

1. Overview

As discussed in the CY 2024 OPPS/ASC proposed rule (88 FR 49867), on January 26, 2021, President Biden issued Executive Order 14001, ''A Sustainable Public Health Supply Chain'' (86 FR 7219), which launched a whole-of-government effort to strengthen the resilience of medical supply chains, especially for pharmaceuticals and simple medical devices. This effort was bolstered subsequently by Executive Orders 14005, 14017, and 14081 (86 FR 7475, 11849, and 25711, respectively). In June 2021, as tasked in Executive Order 14017 on ''America's Supply Chains,'' the Department of Health and Human Services released a review of pharmaceuticals and active pharmaceutical ingredients, analyzing risks in these supply chains and recommending solutions to increase their reliability.[160] In July 2021, as tasked in Executive Order 14001, the Biden–Harris Administration also released the *National Strategy for a Resilient Public Health Supply Chain,* which laid out a roadmap to support reliable access to products for public health in the future, including through prevention and mitigation of medical product shortages.[161]

Over the last several years, shortages for critical medical products have persisted, with the average drug shortage lasting about 1.5 years.[162] For pharmaceuticals, even before the COVID–19 pandemic, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[163] The frequency and severity of these supply disruptions has only been exacerbated over the last few years.[164]

Recent data suggests that hospitals are estimated to spend more than 8.6 million personnel hours and $360 million per year to address drug shortages,[165] which will likely further result in treatment delays and denials, changes in treatment regimens, medication errors,[166] [167] [168] as well as higher rates of hospital-acquired infections and in-hospital mortality.[169] [170] The additional time, labor, and resources required to navigate drug shortages and supply chain disruptions also increase health care costs.[171] [172]

Hospitals' procurement preferences can be leveraged to help foster a more resilient supply of lifesaving drugs and biologicals. With respect to shortages, supply chain resiliency includes having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase—as opposed to relying on ''just-in-time'' inventory-management efficiency at the manufacturer level that can leave supply chains vulnerable to shortage.[173] [174] This concept is especially true for essential medicines, which generally comprise products that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. A hospital's resilient supply can also

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[160] Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[161] Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain,* July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[162] Senate Committee on Homeland Security & Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages,* March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[163] Vizient, *Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals,* June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*

[164] Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain,* July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[165] Vizient, Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals, June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*

[166] American Journal of Health System Pharmacology, *National Survey on the Effect of Oncology Drug Shortages on Cancer Care,* 2013: *https://pubmed.ncbi.nlm.nih.gov/23515514/.*

[167] JCO Oncology Practice, *National Survey on the Effect of Oncology Drug Shortages in Clinical Practice,* 2022: *https://pubmed.ncbi.nlm.nih.gov/35544740/.*

[168] Journal of the American Medical Association, *Association between U.S. Norepinephrine Shortage and Mortality Among Patients with Septic Shock,* 2017: *https://pubmed.ncbi.nlm.nih.gov/28322415/.*

[169] Clinical Infectious Diseases, *The Effect of a Piperacillin/Tazobactam Shortage on Antimicrobial Prescribing and Clostridium difficile Risk in 88 US Medical Centers,* 2017: *https://pubmed.ncbi.nlm.nih.gov/28444166/.*

[170] New England Journal of Medicine, *The Impact of Drug Shortages on Children with Cancer: The Example of Mechlorethamine,* 2012: *https://pubmed.ncbi.nlm.nih.gov/23268661/.*

[171] Senate Committee on Homeland Security & Governmental Affairs, *Short Supply: The Health and National Security Risks of Drug Shortages,* March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[172] Department of Health and Human Services, *ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs,* May 2023: *https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs.*

[173] Department of Health and Human Services, Review of Pharmaceuticals and Active Pharmaceutical Ingredients (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[174] Department of Health and Human Services, National Strategy for a Resilient Public Health Supply Chain, July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

include essential medicines from multiple manufacturers, including the availability of domestic pharmaceutical manufacturing capacity, to diversify the sourcing of essential medicines. We believe it is necessary to support practices that can mitigate the impact of pharmaceutical shortages of essential medicines and promote resiliency to safeguard and improve the care hospitals are able to provide to beneficiaries. Additionally, sustaining sources of domestically sourced medical supplies can help support continued availability in the event of public health emergencies and other disruptions. This concept is consistent with our current policy for domestic National Institute for Occupational Safety and Health (NIOSH) approved surgical N95 respirators (87 FR 72037). Hospitals, as major purchasers and users in the U.S. of essential medicines, can support the existence of domestic sources by sourcing domestically made essential medicines.

When hospitals have insufficient supply of essential medicines, such as during a shortage, care for Medicare beneficiaries can be negatively impacted. To mitigate negative care outcomes in the event of insufficient supply, hospitals can adopt procurement strategies that foster a consistent, safe, stable, and resilient supply of these essential medicines. Such procurement strategies can include provisions to maintain or otherwise provide for extra stock of product (for example, either to maintain or to hold directly at the hospital, arrange contractually for a distributor to hold off-site, or arrange contractually with a wholesaler for a manufacturer to hold product) which can act as a buffer in the event of an unexpected increase in product use or disruption to supply. In the event an essential medicine goes into shortage without existing procurement or substitution strategies for affected drugs, negative patient care outcomes can result in reduced quality of care and, in some instances, increased costs by the Medicare program to provide payment for unnecessary services that could have been avoided had the drug been available to the hospital.

In the CY 2024 OPPS/ASC proposed rule (88 FR 49867), CMS requested public comments on a potential Medicare payment policy that would provide separate payment to hospitals under the IPPS for Medicare's share of the inpatient costs of establishing and maintaining access to a 3-month buffer stock of one or more of 86 essential medicines (referred to herein as the ''CY 2024 Request for Comment''). Under this potential policy, the allowable costs would have included the hospital's reasonable costs of establishing and maintaining buffer stock(s) of the essential medicines but not the cost of the medicines themselves. We stated that we expected that the resources required to establish and maintain access to a buffer stock of essential medicines would generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock. While CMS did not finalize any policy regarding payment under the IPPS and OPPS for establishing and maintaining access to essential medicines, we stated we intended to propose new Conditions of Participation in forthcoming notice and comment rulemaking addressing hospital processes for pharmaceutical supply and that we would continue to consider policies related to buffer stock.

As discussed in the CY 2024 OPPS/ASC final rule, many commenters on the CY 2024 Request for Comment supported CMS's efforts to promote resiliency but expressed concerns regarding the potential for such a payment policy to induce or exacerbate drug shortages through demand shocks to the supply chain. Some commenters stated that a 3-month buffer stock may be inadequate to insulate hospitals from drug shortages, and that the policy may encourage hoarding behaviors and further fragment the existing supply of essential medicines, which would primarily disadvantage smaller, less resourced hospitals (88 FR 82129 through 82130). While commenters stated that a 3-month buffer stock may be inadequate to insulate hospitals from shortages given the duration of many drug shortages, some commenters further stated that even a 6-month buffer stock may not fully protect hospitals in the event of a shortage. Commenters cautioned that drug shortages are difficult to predict and often due to problems at the manufacturer level, which can be compounded by panic buying and hoarding behaviors. Some commenters stated that any buffer stock would need to be sufficiently large to account for the ramp up time that manufacturers need to reestablish supply of a given drug in shortage.

As a first step in this initiative, and based on consideration of the comments we received on the CY 2024 Request for Comment, for cost reporting periods beginning on or after October 1, 2024, we are proposing to establish a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to 6-month buffer stocks of essential medicines to foster a more reliable, resilient supply of these medicines for these hospitals. This proposed separate payment could be provided biweekly or as a lump sum at cost report settlement. As discussed further in section V.J.3. of the preamble of this proposed rule, we are focusing this proposal on small, independent hospitals, many of which are rural, that may lack the resources available to larger hospitals and hospital chains to establish and maintain buffer stocks of essential medicines for use in the event of drug shortages. We believe by limiting separate payment to smaller, independent hospitals, we can also mitigate concerns raised by commenters regarding large demand driven shocks to the supply chain.

The appropriate time to establish a buffer stock for a drug is before it goes into shortage or after a shortage period has ended. In order to further mitigate any potential for the proposed policy to exacerbate existing shortages or contribute to commenters' concerns of hoarding, if an essential medicine is listed as ''Currently in Shortage'' on the FDA Drug Shortages Database,[175] we are proposing that a hospital that *newly* establishes a buffer stock of that medicine while it is in shortage would not be eligible for separate buffer stock payment for that medicine for the duration of the shortage. However, if a hospital had *already* established and was maintaining a buffer stock of that medicine prior to the shortage, we are proposing that the hospital would continue to be eligible for separate buffer stock payment for that medicine for the duration of the shortage. We are proposing that hospital would continue to be eligible even if the number of months of supply of that medicine in the buffer stock were to drop to less than 6 months as the hospital draws down that buffer stock. Once an essential medicine is no longer listed as ''Currently in Shortage'' in the FDA Drug Shortages Database, our proposed policy does not differentiate that essential medicine from other essential medicines and hospitals would be eligible to establish and maintain buffer stocks for the medicine as they would have before the shortage. CMS will conduct provider education regarding additions and deletions to the publicly available FDA Drug Shortages Database to assist hospitals with this proposed policy.

As described in sections V.J.2. and .4. of the preamble of this proposed rule, we are proposing that if the number of

[175] *https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.*

months of supply of medicine in the buffer stock were to drop to less than 6 months for a reason other than the essential medicine(s) actively being listed as ''Currently in Shortage,'' any separate payment to a hospital under this policy would be adjusted based on the proportion of the cost reporting period for which the hospital did maintain the 6-month buffer stock of that essential medicine.

We are proposing to make this separate payment under the IPPS for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. We are not proposing to make this payment adjustment budget neutral under the IPPS.

2. Proposed List of Essential Medicines

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment,* as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute's (ARMI's) Next Foundry for American Biotechnology, prioritized 86 essential medicines (hereinafter referred to as the ''ARMI List'' or ''ARMI's List'') from the Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs (hereinafter referred to as the ''E.O. 13944 List''), as developed under the E.O. by the U.S. Food and Drug Administration (FDA).[176]

The ARMI List is a prioritized list of 86 medicines that are either critical for minimum patient care in acute settings or important for acute care with no comparable alternatives available. The medicines included in the ARMI List were considered, by consensus, to be most critically needed for typical acute patient care. In this context, acute patient care was defined as: rescue and/or lifesaving use (that is, Intensive Care Units, Cardiac/Coronary Care Units, and Emergency Departments), stabilizing patients in hospital continued care to enable discharge, and urgent or emergency surgery.

Development of the ARMI List focused on assessing the clinical criticality and supply chains of small molecules and therapeutic biologics. The development of the ARMI List was informed by meetings with multiple key pharmaceutical supply chain stakeholders (for example, manufacturers, group purchasing organizations, wholesale distributors, providers, pharmacies), surveys and workshops with groups of clinicians and industry stakeholders, public feedback on the E.O. 13944 List (provided during a public comment period starting in October 2020), and other research.

We are proposing that for purposes of the proposed separate payment under the IPPS, the costs of buffer stocks that would be eligible for separate payment are the additional resource costs of establishing and maintaining access to a 6-month buffer stock for any eligible medicines on ARMI's List of 86 essential medicines, including any subsequent revisions to that list of medicines. As previously discussed, the ARMI List represents a prioritized list of 86 medicines that were considered, by consensus, to be most critically needed for typical acute patient care. At this time, we believe that the ARMI List constitutes an appropriate set of medicines to initially prioritize under this proposed payment policy in order to help insulate small, independent hospitals, and the inpatient care they provide, from the negative effects of drug shortages.

As noted earlier, the appropriate time to establish a buffer stock for a drug is before it goes into shortage or after a shortage period has ended. If an essential medicine is listed as ''Currently in Shortage'' on the FDA Drug Shortages Database, we are proposing that a hospital that *newly* establishes a buffer stock of that medicine while it is in shortage would not be eligible for separate buffer stock payment for that medicine for the duration of the shortage. However, if a hospital had *already* established and was maintaining a buffer stock of that medicine prior to the shortage, we are proposing that the hospital would continue to be eligible for separate buffer stock payment for that medicine for the duration of the shortage as the hospital draws down that buffer stock even if the number of months of supply of that medicine in the buffer stock were to drop to less than 6 months. By limiting eligibility in this way, we believe that we can both insulate smaller hospitals from short-term drug shortages and mitigate the potential for the proposed policy to exacerbate existing shortages or contribute to concerns of hoarding.

As an illustrative example, suppose a hospital established and maintained 6-month buffer stocks for five essential medicines. However, one of those essential medicines was subsequently listed as ''Currently in Shortage'' on the FDA Drug Shortages Database. The hospital would no longer be required to maintain a 6-month buffer stock of the essential medicine that is in shortage to receive separate payment for maintaining the buffer stock of that essential medicine during the period of shortage. The hospital would continue to be eligible for the separate payment from CMS for the buffer stock for that medicine during the period of shortage as it draws down its established buffer stock of the medicine in shortage as needed. However, the hospital would be required to maintain buffer stocks of no less than 6 months for the other four essential medicines that are not in shortage to be eligible to receive separate payment for those four medicines.

Because medicine can remain on the FDA Drug Shortage Database for years, we request comments on the duration that CMS should continue to pay hospitals for the maintenance of a less than 6-month buffer stock of the essential medicine if it is ''Currently in Shortage.'' We also request comments on if there is a quantity or dosage minimum floor where CMS should no longer pay to maintain a 6-month buffer stock of the essential medicine if it is ''Currently in Shortage.'' For example, if a hospital has one remaining dose of a drug ''Currently in Shortage'' and that drug remains in shortage on the FDA Drug Shortage Database for 5 years, should there be limits on how much and for how long CMS would pay a hospital for a 6-month buffer stock?

We are proposing that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment under this policy for the IPPS shares of the costs of establishing and maintaining access to 6-month buffer stocks as of the date the updated ARMI List is published. To the extent that in the future other medicines or lists are identified for eligibility in future iterations of this policy, we seek comment on the potential mechanism and timing for incorporating those updates. Comments may consider, among other factors, medicines that were excluded from the ARMI List, the E.O. 13944 List, or both. For example, some categories from the E.O. 13944 List—including Blood and Blood Products, Fractionated Plasma Products, Vaccines, and Volume Expanders—were excluded from the ARMI List due to

[176] *https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs.*

differences in their supply chains. Additionally, other categories were identified as not needed for routine/typical acute patient care (that is, Biological Threat Medical Countermeasures, Burn and Blast Injuries, Chemical Threat Medical Countermeasures, Pandemic Influenza Medical Countermeasures, Radiologic-Nuclear Threat Medical Countermeasures). The ARMI List does not include certain medicines that have recently been in shortage and that may be considered essential and are more prevalent in specific care settings other than an inpatient hospital, such as drugs used in oncology care on an outpatient basis. Further, there are medicines that are not included on the ARMI List nor the E.O. 13944 List, such as buprenorphine-based medications for treatment of substance use disorder. We seek comment on whether eligibility for separate payment for the IPPS share of the costs of establishing and maintaining access to 6-month buffer stocks of essential medicines should include oncology drugs or other types of drugs not currently on the ARMI List.

As noted earlier, CMS will conduct provider education regarding additions and deletions to the publicly available FDA Drug Shortages Database to assist hospitals with this proposed policy.

3. Hospital Eligibility

Commenters on the CY 2024 Request for Comment (88 FR 82129 through 82130) raised a number of concerns relating to access to essential medicines for small hospitals and potential hoarding behaviors among better resourced hospitals. Commenters also cautioned against the potential for the policy to cause demand-driven shocks to the pharmaceutical supply chain, exacerbating pharmaceutical access issues for hospitals, which they claimed would disproportionately impact smaller hospitals due to their smaller purchasing power. As hospitals and hospital systems increase in size through expansion of bed count and/or consolidation and vertical integration with other hospitals and health systems, they accrue bargaining leverage for payment negotiations and thereby increase their purchasing power.[177] Those smaller (and often rural) hospitals that lack this increased purchasing power are faced with potentially lower payments from payers and less operating capital.[178] To address this concern, and attempt to better insulate these smaller, independent hospitals against future supply disruptions of essential medicines, we are proposing to limit eligibility for separate payment for the resource costs of establishing and maintaining access to buffer stocks of essential medicines to small, independent hospitals that are paid under the IPPS, as defined later in this section. As many of these small, independent hospitals are located in rural areas, we also expect this policy to support rural hospitals, in line with the rural health strategy of the Biden-Harris Administration.[179] [180]

We believe that by focusing eligibility on small, independent hospitals, we can both support these types of hospitals in their efforts to provide patient care during drug shortages and lessen any potential demand shocks to the pharmaceutical supply chain because the buffer stocks these hospitals would require are likely smaller compared to larger hospitals and hospital chains. As discussed further in the regulatory impact analysis associated with this proposed policy in section I.G.6. of Appendix A of this proposed rule, we identified 493 potentially eligible hospitals based on FY 2021 hospital cost report data. Of these hospitals, 249 were identified as geographically rural, 6 were identified as geographically urban but reclassified as rural (under our reclassification regulations at § 412.103), and 238 were identified as geographically urban without a reclassification as rural. These hospitals had 216,557 Medicare discharges in total and an average of 442 Medicare discharges per hospital for the FY 2021 cost reporting year.

Small Hospital: For the purposes of this policy, we propose to define a small hospital as one with not more than 100 beds. This definition is consistent with the definition of a small hospital used for Medicare-dependent, small rural hospitals (MDH) in section 1886(d)(5)(G)(iv)(II) of the Act. Consistent with the MDH regulations at § 412.108(a)(1)(ii), we propose that a hospital would need to have 100 or fewer beds as defined in § 412.105(b) during the cost reporting period for which it is seeking the payment adjustment to be considered a small hospital for purposes of this payment adjustment. We request comment on using criteria other than the MDH bed size criterion to identify small hospitals for the purposes of this proposed payment policy.

Independent Hospital: For the purposes of this policy, we propose to define an independent hospital as one that is not part of a chain organization, as defined for purposes of hospital cost reporting. A chain organization is defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization. This proposed definition is the definition of chain organization in CMS Pub 15–1, Provider Reimbursement Manual, Chapter 21, Cost Related to Patient Care § 2150: ''Home Office Costs—Chain Operations'' and used by a hospital when completing its cost report.

Because this proposed definition is the definition of chain organization used by a hospital when filling out its cost report, to operationalize our proposed separate payment policy, we propose that any hospital that appropriately answers ''yes'' (denoted ''Y'') to line 140 column 1 or fills out any part of lines 141 through line 143 on Worksheet S–2, Part I, on Form CMS–2552–10 is considered to be part of a chain organization and not independent, and therefore not eligible for separate payment under this proposal. Please see Table V.J.-01 for a partial example of this section of Form CMS–2552–10.

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[177] U.S. Congress, U.S. House of Representatives Committee on Ways and Means, Subcommittee on Health, Health Care Consolidation: The Changing Landscape of the U.S. Health Care System, May 2023: *https://www.rand.org/content/dam/rand/pubs/testimonies/CTA2700/CTA2770-1/RAND_CTA2770-1.pdf.*

[178] American Hospital Association, Rural Hospital Closures Threaten Access: Solutions to Preserve Care in Local Communities, September 2022: *https://www.aha.org/system/files/media/file/2022/09/rural-hospital-closures-threaten-access-report.pdf.*

[179] The White House, *The Biden-Harris Administration is taking actions to improve the health of rural communities and help rural health care providers stay open,* November 2023: *https://www.hhs.gov/about/news/2023/11/03/department-health-human-services-actions-support-rural-america-rural-health-care-providers.html.*

[180] The White House, *Fact Sheet: Biden Administration Takes Steps to Address Covid-19 in Rural America and Build Rural Health Back Better,* August 2021: *https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/13/fact-sheet-biden-administration-takes-steps-to-address-covid-19-in-rural-america-and-build-rural-health-back-better/.*

Table V.J.-01.: Lines 140-143 of Worksheet S-2, Part 1

All Providers		1	2
140	Are there any related organization or home office costs as defined in CMS Pub. 15-1, chapter 10? Enter "Y" for yes or "N" for no in column 1. If yes, and home office costs are claimed, enter in column 2 the home office chain number.	("Y" or "N")	(Home office chain number)
If this facility is part of a chain organization, enter on lines 141 through 143 the name and address of the home office and enter the home office contractor name and contractor number.			
141	Name:	Contractor's Name:	Contractor's Number:
142	Street:	P.O. Box:	
143	City:	State:	Zip Code:

Thus, we propose that in order to be eligible for this separate payment, under this policy, a hospital would need to be a small hospital with 100 or fewer beds and meet the definition of independent described previously. We seek comment on our proposed eligibility criteria and proposed definition of a small, independent hospital.

We note that critical access hospitals (CAHs) are paid for inpatient and outpatient services at 101 percent of Medicare's share of reasonable costs, including Medicare's share of the reasonable costs of establishing and maintaining access to buffer stocks of medicines. We seek comment on the use of buffer stocks by CAHs, including the medicines in the buffer stocks, the costs of establishing and maintaining the buffer stocks, whether CAHs tend to contract out this activity, and any barriers that CAHs may face in establishing and maintaining access to buffer stocks.

4. Size of the Buffer Stock

As summarized in the CY 2024 OPPS/ASC final rule and section V.J.1. of the preamble of this proposed rule, some commenters on the CY 2024 Request for Comment expressed concerns that a 3-month supply of essential medicines may not be sufficient to adequately insulate hospitals from the detrimental effects of future drug shortages. Commenters stated that drug shortages often persist for durations of time in excess of 3 months, such that a 3-month buffer stock may be inadequate to insulate hospitals from the longer-term effects of drug shortages. As noted in section V.J.1. of the preamble of this proposed rule, drug shortages generally persist for many months, and some research suggests that these shortages last for an average of 1.5 years. Accordingly, we believe a buffer stock of at least 6 months would better support small, independent hospitals in contending with future shortages. To better address commenters' concerns and hospital needs during drug shortages, we are proposing separate payment for the costs of establishing and maintaining access to a buffer stock that is sufficient for no less than a 6-month period of time for each of one or more essential medicines. As discussed in section V.J.5 of the preamble of this proposed rule, we are also seeking comments on whether a phase-in approach that, for example, would provide separate payment for establishing and maintaining access to a 3-month supply for the first year in which the policy is implemented and a 6-month supply for all subsequent years would be appropriate.

In estimating the amount of a buffer stock needed for each essential medicine, the hospital should consider that the amount needed to maintain a buffer stock could vary month to month and throughout the applicable months of the cost reporting period; that is, a hospital's historical use of a medicine may indicate that it is typically needed more often in January than June, for example. Accordingly, the size of the buffer stock should reflect this anticipated variation and be based on a reasonable estimate of the hospital's need for that essential medicine in the upcoming 6-month period. This estimate would be determined by the hospital and could be based on the historical usage of the essential medicine by the hospital for that 6-month period in a prior year, or another reasonable method to estimate its need for that upcoming period. If a hospital did not maintain a 6-month buffer stock of an essential medicine for an entire cost reporting period, any separate payment to the hospital under this policy would be adjusted based on the proportion of the cost reporting period for which the hospital did maintain the 6-month buffer stock of that essential medicine. As described in section V.J.2 of the preamble of this proposed rule, in the event that a hospital is not able to maintain a buffer stock of at least 6 months due to one or more of their chosen medicine(s) being listed as ''Currently in Shortage'' on the FDA's Drug Shortage Database after establishment of the buffer stock under this policy, the hospital would continue to be eligible for the buffer stock payment for the medicine(s) in shortage as the hospital draws down the buffer stock even if the number of months of supply of that medicine in the buffer stock were to drop to less than 6 months. Hospitals would be permitted to use multiple contracts to establish and maintain at least a 6-month buffer stock for any given essential medicine.

5. Proposed Separate Payment Under IPPS for Establishing and Maintaining Access to Buffer Stocks of Essential Medicines

As discussed in the CY 2024 Request for Comment, CMS requested public comments on a potential separate payment under the IPPS for the additional, reasonable costs of establishing and maintaining a 3-month buffer stock of one or more essential medicine(s). We stated that participating hospitals could establish and maintain their buffer stocks directly, or through contractual arrangements with pharmaceutical distributors, intermediaries, or manufacturers.

We received comments in response to the CY 2024 Request for Comment stating that hospitals that maintain buffer stocks of essential medicines typically do so through upstream entities, such as pharmaceutical group purchasing organizations and manufacturers. Furthermore, these commenters stated that hospitals typically lack the capacity to stockpile large quantities of essential medicines directly. Some of these commenters

stated that any buffer stocks established under the potential policy should be maintained by upstream intermediaries or a neutral third party instead of directly maintained by hospitals, as they stated that these upstream intermediaries are generally better positioned and equipped to maintain these buffer stocks. While other commenters were receptive to directly maintaining their buffer stock(s) or indicated that they already maintained substantial buffer stocks of medicines, these commenters were generally larger, better resourced hospitals or hospital systems.

We agree with commenters that pharmaceutical intermediaries and manufacturers are generally better positioned to establish and maintain larger (for example, 6-month or greater) buffer stocks of essential medicines, as small, independent hospitals may generally lack the space, staff, and specific equipment (like large-scale refrigeration and large, onsite storage) to directly maintain 6-month buffer stock(s) of essential medicine(s). While we anticipate that most hospitals that elect to establish and maintain buffer stocks under this policy will do so through contractual arrangements with pharmaceutical intermediaries, manufacturers, and distributors, we are proposing that the additional resource costs associated with directly maintaining 6-month buffer stock(s) of essential medicine(s) would also be eligible for separate payment under this policy. Accordingly, we are proposing that for purposes of the proposed separate payment under the IPPS to small, independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to 6-month buffer stocks of essential medicines, those costs associated with establishing and maintaining access to 6-month buffer stocks either directly or through contractual arrangements with pharmaceutical manufacturers, intermediaries, or distributors would be eligible for additional payment under this policy. These costs do not include the cost of the medicines themselves which would continue to be paid in the current manner. We also note that the proposed payment is only for the IPPS share of the costs of establishing and maintaining access to buffer stock(s) of one or more essential medicine(s).

The costs associated with directly establishing and maintaining a buffer stock may include utilities like cold chain storage and heating, ventilation, and air conditioning, warehouse space, refrigeration, management of stock including stock rotation, managing expiration dates, and managing recalls, administrative costs related to contracting and record-keeping, and dedicated staff for maintaining the buffer stock(s). We request comments on other types of costs intrinsic to directly establishing buffer stocks of essential medicines that should be considered eligible for purposes of separate payment under this policy. We also request comment regarding whether staff costs would increase with the number of essential medicines in buffer stock, and whether there would be efficiencies if multiple hospitals elect to establish buffer stocks of essential medicines with the same pharmaceutical manufacturer, intermediary, or distributor.

We also request comment on whether this proposed policy should be phased in by the size of the buffer stock to address concerns about infrastructure investments that may be needed to store and maintain the supply. For example, under a phased approach, separate payment could be made available for establishing and maintaining access to a 3-month supply for the first year in which the policy is implemented and a 6-month supply for all subsequent years. We also refer readers to the Collection of Information Requirements in section XII.B.2. of the preamble of this proposed rule regarding the estimated burden associated with this policy proposal and seek comment on whether there are any other potential methods for hospitals to report costs included under this policy besides the forthcoming supplemental cost reporting worksheet.

Currently, payment for the resources required to establish and maintain access to medically reasonable and necessary drugs and biologicals is generally part of the IPPS payment. As noted in section V.J.2. of the preamble of this proposed rule, we expect that the resources required to establish and maintain access to buffer stocks of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such buffer stocks. Given these additional resource costs and our concern that small, independent hospitals may lack the resources available to larger hospitals and hospital chains to establish buffer stocks of essential medicines, we believe it is appropriate to propose to pay these hospitals separately for the additional resource costs associated with voluntarily establishing and maintaining access, either directly or through contractual arrangements, to buffer stocks of essential medicines. As also noted in section V.J.2 of the preamble of this proposed rule, we are proposing that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment under this policy for the IPPS shares of the costs of establishing and maintaining access to 6-month buffer stocks as of the date the updated ARMI List is published. Any medicine(s) that are removed from the ARMI List in any future updates to the list would no longer be eligible for separate payment under this policy for the IPPS shares of the costs of establishing and maintaining access to 6-month buffer stocks as of the date the updated ARMI List is published.

CMS is proposing to base the IPPS payment under this policy on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators, which is based on the IPPS and OPPS shares of the difference in cost between domestic and non-domestic NIOSH approved surgical N95 respirators for the cost reporting period in which costs are claimed (87 FR 72037). The hospital would report these costs to CMS on the forthcoming supplemental cost reporting worksheet associated with this proposed policy. The hospital's costs may include costs associated with contractual arrangements between the hospital and a manufacturer, distributor, or intermediary or costs associated with directly establishing and maintaining buffer stock(s). These costs would not include the costs of the essential medicine itself, which would continue to be paid in the current manner.

If a hospital establishes and maintains access to buffer stock(s) of essential medicine(s) through contractual arrangements with pharmaceutical manufacturers, intermediaries, or distributors, the hospital would be required to disaggregate the costs specific to establishing and maintaining the buffer stock(s) from the remainder of the costs present on the contract for purposes of reporting these disaggregated costs under this proposed policy. This disaggregated information, reported by the hospital on the new supplemental cost reporting worksheet, along with existing information already collected on the cost report, would be used to calculate a Medicare payment for the IPPS share of the hospital's costs of establishing and maintaining access to the buffer stock(s) of essential medicine(s).

If a hospital contracts with one or more manufacturers or wholesalers or other intermediaries to establish and maintain 6-month buffer stocks of one or more essential medicines, the hospital must clearly identify those costs separately from the costs of other provisions of the contract(s). As a simplified example for purposes of illustration, suppose a hospital has a $500,000 contract with a pharmaceutical wholesaler. The contract is for pharmaceutical products, 50 of which are qualifying essential medicines. Additionally, the contract contains a provision for the wholesaler to establish and maintain 6-month buffer stocks of those 50 essential medicines on the hospital's behalf. The contract further specifies that $10,000 of the $500,000 is for the provision of the contract that establishes and maintains the 6-month buffer stocks of those 50 essential medicines. This $10,000 amount does not include any costs to the hospital for the drugs themselves which, as previously noted, would continue to be paid in the current manner. Under this proposal, the hospital would report the $10,000 cost for establishing and maintaining the 6-month buffer stocks of the 50 essential medicines on the supplemental cost reporting worksheet. That $10,000 cost, in addition to other information already existing on the cost report, would be used to calculate the additional payment under this policy including the hospital-specific Medicare IPPS share percentage of this cost, expressed as the percentage of inpatient Medicare costs to total hospital costs. On average for the small, independent hospitals that are eligible for this policy, the Medicare IPPS share percentage is approximately 11 percent.

If a hospital chooses to directly establish and maintain buffer stock(s) of one or more essential medicines, the hospital would be required to report the additional costs associated with establishing and maintaining its buffer stock(s) on the supplemental cost reporting form. The hospital should clearly specify the total additional resource costs to establish and maintain its 6-month buffer stock(s) of essential medicine(s). As in the previous example, this amount should not include the cost of the essential medicine(s) themselves and would be used, along with other information already existing on the cost report, to calculate the additional payment under this policy.

Additionally, we would anticipate that when a hospital contracts with one or more manufacturers or wholesalers or other intermediaries to establish and maintain 6-month buffer stocks of one or more essential medicines, it would ensure that a discrete buffer stock is maintained for that hospital. For example, if two hospitals held contracts with a manufacturer arranging for 6-month buffer stocks of certain essential medicines, the hospitals would verify that the manufacturer is maintaining sufficient total buffer stock to account for the 6-month demand of both hospitals in aggregate.

We seek to support the establishment of buffer stocks when drugs are not currently in shortage in order to promote the overall resiliency of drug supply chains. As previously discussed, we are proposing that buffer stocks for any of the essential medicines on the ARMI List that are listed as ''Currently in Shortage'' on the FDA Drug Shortages Database would not be eligible for additional payment under this policy for a hospital's cost reporting period unless the hospital had already established and was maintaining a buffer stock of that medicine prior to the shortage.

Additionally, we are proposing that any essential medicine(s) for which a hospital has successfully established and maintained a buffer stock(s) of at least 6 months that is subsequently listed as ''Currently in Shortage'' on the FDA Drug Shortages Database would be exempt from the requirement to maintain a 6-month supply of such essential medicine(s) for the duration of the period in which the medicine is in shortage. We are interested in public comments on the burden associated with hospitals' monitoring of the FDA Drug Shortage Database, and excluding from the cost report any resource costs associated with maintaining a buffer stock of an essential medicine that was listed as ''Currently in Shortage,'' except where the hospital had already established and was maintaining a 6-month buffer stock of that medicine prior to the shortage. As of the date that medicine is no longer listed as ''Currently in Shortage,'' eligibility for separate payment to the hospital for the drug in shortage would be prospectively adjusted based on the proportion of the cost reporting period for which the hospital does maintain the 6-month buffer stock of that essential medicine. Once an essential medicine is no longer listed as ''Currently in Shortage'' in the FDA Drug Shortages Database, our proposed policy does not differentiate that essential medicine from other essential medicines. However, we also seek comment on whether some minimum period, such as 6 months, should elapse after a shortage of a given essential medicine is resolved before that medicine can become eligible for separate payment under this proposed policy.

We are proposing to make separate payments for the IPPS shares of these additional resource costs of establishing and maintaining access to buffer stocks of essential medicines. Payment could be provided as a lump sum at cost report settlement or biweekly as interim lump-sum payments to the hospital, which would be reconciled at cost report settlement. In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's share of these additional inpatient costs at cost report settlement. Alternatively, a provider may make a request for biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the Medicare Administrative Contractor (MAC) consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount would be based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15–1 § 2405.2 for additional information). The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that would be included on the new supplemental cost reporting form. CMS will separately seek comment through the Paperwork Reduction Act (PRA) process on a supplemental cost reporting form that would be used for this purpose. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available. This is consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15–1 § 2405.2. It is also consistent with the payment adjustment for domestically sourced NIOSH approved surgical N95 respirators (87 FR 72037).

We are proposing to codify this payment adjustment in the regulations

by adding new paragraph (g) to 42 CFR 412.113 to state the following:

- Essential medicines are the 86 medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022, and any subsequent revisions to that list of medicines. A buffer stock of essential medicines for a hospital is a supply, for no less than a 6-month period, of one or more essential medicines.
- The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients or arrange contractually for such a buffer stock to be held by another entity for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves.
- For cost reporting periods beginning on or after October 1, 2024, a payment adjustment to a small, independent hospital for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines is made as described in paragraph (g)(4) of this section. For purposes of this section, a *small, independent hospital* is a hospital with 100 or fewer beds as defined in § 412.105(b) during the cost reporting period that is not part of a chain organization, defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.
- The payment adjustment is based on the estimated reasonable cost incurred by the hospital for establishing and maintaining access to buffer stocks of essential medicines during the cost reporting period.

We are also proposing to make conforming changes to 42 CFR 412.1(a) and 412.2(f) to reflect this proposed payment adjustment for small, independent hospitals for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines.

In summary, for cost reporting periods beginning on or after October 1, 2024, we are proposing to establish a separate payment under the IPPS to small, independent hospitals for the additional resource costs involved in voluntarily establishing and maintaining access to 6-month buffer stocks of essential medicines, either directly or through contractual arrangements with a manufacturer, distributor, or intermediary. We are proposing that the costs of buffer stocks that are eligible for separate payment are the costs of buffer stocks for one or more of the medicines on ARMI's List of 86 essential medicines. The separate payment would be for the IPPS share of the additional costs and could be issued in a lump sum, or as biweekly payments to be reconciled at cost report settlement. The separate payment would not apply to buffer stocks of any of the essential medicines on the ARMI List that are currently listed as ''Currently in Shortage'' on the FDA Drug Shortages Database unless a hospital had already established and was maintaining a 6-month buffer stock of that medicine prior to the shortage. Once an essential medicine is no longer listed as ''Currently in Shortage'' in the FDA Drug Shortages Database, our proposed policy does not differentiate that essential medicine from other essential medicines and hospitals would be eligible to establish and maintain buffer stocks for the medicine as they would have before the shortage. CMS will separately seek comment through the PRA process on a supplemental cost reporting form for this proposed payment.

K. Hospital Readmissions Reduction Program

1. Regulatory Background

Section 3025 of the Patient Protection and Affordable Care Act, as amended by section 10309 of the Patient Protection and Affordable Care Act, added section 1886(q) to the Act, which establishes the Hospital Readmissions Reduction Program effective for discharges from applicable hospitals beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals may be reduced to account for certain excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a general overview of the Hospital Readmissions Reduction Program. We also refer readers to 42 CFR 412.152 through 412.154 for codified Hospital Readmissions Reduction Program requirements.

2. Notice of No Program Proposals or Updates

There are no proposals or updates in this proposed rule for the Hospital Readmissions Reduction Program. We refer readers to section I.G.7. of Appendix A of the proposed rule for an updated estimate of the financial impact of using the proportion of dually eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2025 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2020, through June 30, 2023).

L. Hospital Value-Based Purchasing (VBP) Program

1. Background

a. Overview

For background on the Hospital VBP Program, we refer readers to the CMS website at: *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing.* We also refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

b. FY 2025 Program Year Payment Details

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2025 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2025 is approximately $1.7 billion, based on the December 2023 update of the FY 2023 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). We note that these proxy adjustment factors will not be used to adjust hospital payments. These proxy value-based incentive payment adjustment factors were calculated using the historical baseline and performance periods for the FY 2024 Hospital VBP Program. These proxy factors were calculated using the December 2023 update to the FY 2023 MedPAR file. The slope of the linear exchange function used to calculate

these proxy factors was 4.7270521828, and the estimated amount available for value-based incentive payments to hospitals for FY 2025 is approximately $1.7 billion. We intend to include an update to this table, as Table 16A, with the FY 2025 IPPS/LTCH PPS final rule, to reflect changes based on the March 2024 update to the FY 2023 MedPAR file. We will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2025 Hospital VBP Program. We expect that Table 16B will be posted on the CMS website in Fall 2024.

2. Previously Adopted Quality Measures for the Hospital VBP Program

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49110 through 49111) for summaries of previously adopted measures for the FY 2025 and FY 2026 program years and to the FY 2024 IPPS/LTCH PPS final rule for summaries of newly adopted measures beginning with the FY 2026 program year (88 FR 59081 through 59083). We are not proposing any changes to the measure set. Table V.L.–01 summarizes the previously adopted Hospital VBP Program measure set for the FY2025 program year.

TABLE V.L.-01: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2025 PROGRAM YEAR

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridioides difficile* Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

As discussed in section IX.B.2.g(2) of the preamble of this proposed rule, we are proposing to adopt updates to the HCAHPS Survey measure beginning with the FY 2030 program year. We are also proposing to adopt updates to the HCAHPS Survey measure in the Hospital Inpatient Quality Reporting (IQR) Program, beginning with the FY 2027 program year, as described in section IX.B.2.e of the preamble of this proposed rule. We are also proposing to modify Hospital VBP Program scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years to score hospitals on only those dimensions of the survey that would remain unchanged from the current version, as

described in section IX.B.2.f of the preamble of this proposed rule. Lastly, we are also proposing to modify the scoring in FY 2030 to account for the adoption of the proposed modifications to the HCAHPS Survey measure that would result in a total of nine survey dimensions for the updated HCAHPS Survey measure in the Hospital VBP Program, which is described in section IX.B.2.g(3) of the preamble of this proposed rule. Table V.L.–02 summarizes the previously adopted Hospital VBP Program measures for the FY 2026 through FY 2030 program years.

TABLE V.L.-02: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2026 THROUGH FY 2030 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridioides difficile* Infection (CDI) Outcome Measure	1717
SEP-1	Severe Sepsis and Septic Shock: Management Bundle	0500
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

* In sections IX.B.2.f and IX.B.2.g of the preamble of this proposed rule, we are proposing several updates with regard to the HCAHPS Survey in the Hospital VBP Program, including modifying scoring while the updated version of the measure would be adopted in the Hospital IQR Program for the FY 2027 through FY 2029 program years. We are also proposing to adopt the updated version of the measure and to modify scoring to account for the updates in the Hospital VBP Program beginning in FY 2030. We refer readers to Table IX.B.2-03 in section IX.B.2.g(2) of the preamble of this proposed rule for the timelines for current and newly proposed HCAHPS Survey dimensions for the Hospital VBP Program.

3. Baseline and Performance Periods for the FY 2026 Through FY 2030 Program Years

a. Background

We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59084 through 59087) for previously adopted baseline and performance periods for the FY 2025 through FY 2029 program years. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998) in which we finalized a schedule for all future baseline and performance periods for all measures.

b. Summary of Baseline and Performance Periods for the FY 2026 Through FY 2030 Program Years

Tables V.L.–03, V.L.–04, V.L.–05, V.L.–06, and V.L.–07 summarize the baseline and performance periods that we have previously adopted.

TABLE V.L.-03: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2026 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2016 – June 30, 2019	July 1, 2021 – June 30, 2024
COMP-HIP-KNEE	April 1, 2016 – March 31, 2019	April 1, 2021 – March 31, 2024
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
SEP-1	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024

TABLE V.L.-04: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2027 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS*	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2017 – June 30, 2020**	July 1, 2022 – June 30, 2025
COMP-HIP-KNEE	April 1, 2017 – March 31, 2020**	April 1, 2022 – March 31, 2025
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025
SEP-1	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025

* In section IX.B.2.f of the preamble of this proposed rule, we are proposing that for the FY 2027 program year, we would only score on the six dimensions of the HCAHPS Survey that would remain unchanged from the current version.

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.L.-05: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS*	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT3-0-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2018 – June 30, 2021**	July 1, 2023 – June 30, 2026
COMP-HIP-KNEE	April 1, 2018 – March 31, 2021**	April 1, 2023 – March 31, 2026
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
SEP-1	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026

* In section IX.B.2.f of the preamble of this proposed rule, we are proposing to we are proposing that for the FY 2028 program year, we would only score on the six dimensions of the HCAHPS Survey that would remain unchanged from the current version.

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.L.-06: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2029 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS*	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Clinical Outcomes Domain		
Mortality measures (MOR-T30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2019 – June 30, 2022**	July 1, 2024 – June 30, 2027
COMP-HIP-KNEE	April 1, 2019 – March 31, 2022**	April 1, 2024 – March 31, 2027
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
SEP-1	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027

* In section IX.B.2.f of the preamble of this proposed rule, we are proposing that for the FY 2029 program year, we would only score on the six dimensions of the HCAHPS Survey that would remain unchanged from the current version.

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.L.-07: BASELINE AND PERFORMANCE PERIODS FOR THE FY 2030 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS*	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT3-0-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2020 – June 30, 2023	July 1, 2025 – June 30, 2028
COMP-HIP-KNEE	April 1, 2020 – March 31, 2023	April 1, 2025 – March 31, 2028
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
SEP-1	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2026 – December 31, 2026	January 1, 2028 – December 31, 2028

* In section IX.B.2.g of the preamble of this proposed rule, we are proposing to adopt the substantive updates to the HCAHPS Survey beginning with the FY 2030 program year.

4. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49115 through 49118) for previously established performance standards for the FY 2025 program year. We also refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59089 through 59090) for the previously established performance standards for the FY 2026 program year. We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Previously and Newly Estimated Performance Standards for the FY 2027 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45294 through 45295), we established performance standards for the FY 2027 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established and newly estimated performance standards for the FY 2027 program year are set out in Tables V.L.–08 and V.L.–09.

TABLE V.L.-08: PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain		
CAUTI*,**	0.506	0
CLABSI*,**	0.602	0
CDI*	0.363	0
MRSA Bacteremia*	0.675	0
Colon and Abdominal Hysterectomy SSI*	0.74 0.872	0
SEP-1***	0.612069	0.855541
Clinical Outcomes Domain #		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
** We note that the numerical values for the performance standards for the HAI measures in the preamble of this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2025 IPPS/LTCH PPS final rule. These estimates are based on October 2022 through September 2023 data.
*** We note that the numerical values for the performance standards for the SEP-1 measures in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2025 IPPS/LTCH PPS final rule. These estimates are based on October 2022 through September 2023 data.
# As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 5297 through 45299), we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

As discussed in section IX.B.2.f of the preamble of this proposed rule, we are proposing to modify the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years while the proposed updates to the survey would be publicly reported under the Hospital IQR Program. Scoring would be modified to only score hospitals on the six Hospital VBP Program dimensions of the HCAHPS Survey that would remain unchanged from the current version. These six dimensions of the HCAHPS Survey for the Hospital VBP Program would be:

- ''Communication with Nurses,''
- ''Communication with Doctors,''
- ''Communication about Medicines,''
- ''Discharge Information,''
- ''Cleanliness and Quietness,'' and
- ''Overall Rating.''

We are proposing to exclude the ''Responsiveness of Hospital Staff'' and ''Care Transition'' dimensions from scoring in the Hospital VBP Program's HCAHPS Survey measure in the Person and Community Engagement domain for the FY 2027 through FY 2029 program years. This would allow hospitals to be scored on only those dimensions of the survey in the Hospital VBP Program that would remain unchanged from the current version of the survey while the updated HCAHPS Survey is publicly reported on under the Hospital IQR Program for one year as required by statute. We are also proposing to adopt the updated version of the HCAHPS Survey measure for use in the Hospital VBP Program beginning in FY 2030 as outlined in section IX.B.2.g of this proposed rule.

Scoring would be modified such that for each of the six dimensions listed previously, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which would be summed across these six dimensions to create a pre-normalized HCAHPS Base Score of 0–60 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score would then be multiplied by 8/6 (1.3333333) and rounded according to standard rules (values of 0.5 and higher are rounded

up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the six dimensions would be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would be calculated in the same manner as the current method and would continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score would consider scores across the six unchanged dimensions of the Person and Community Engagement domain. The final element of the scoring formula, which would remain unchanged from the current formula, would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points. The method for calculating the performance standards for the six dimensions would remain unchanged. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for our methodology for calculating performance standards. The estimated performance standards for the six dimensions that are proposed to be scored on for the FY 2027 program year are set out in Table V.L.–09.

TABLE V.L.-09: ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN

HCAHPS Survey Dimension*[1]	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	55.66	77.16	86.14
Communication with Doctors	56.23	77.39	86.28
Responsiveness of Hospital Staff**	X	X	X
Communication about Medicines	32.59	58.17	70.34
Hospital Cleanliness & Quietness	41.54	63.30	77.64
Discharge Information	64.34	85.86	91.44
Care Transition**	X	X	X
Overall Rating of Hospital	34.46	68.48	83.89

[1] Includes IPPS hospitals with 100+ completed surveys from patients discharged between October 2022 and September 2023.
* We note that the numerical values for the performance standards for the HCAHPS Survey in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2025 IPPS/LTCH PPS final rule. These estimates are based on 10/1/2022- 9/30/2023 data.
** For FY 2027, we are proposing to only score on the six dimensions of the HCAHPS Survey measure that would remain unchanged from the current version until the proposed updates to the survey measure can be adopted beginning with FY 2030. Therefore, we are not reporting estimated performance standards for dimensions that would not be scored. We note that if the updates to the HCAHPS Survey measure are not finalized, we will publish the performance standards for the "Responsiveness of Hospital Staff" and "Care Transition" dimensions in the FY 2025 IPPS/LTCH PPS final rule.

c. Previously Established Performance Standards for Certain Measures for the FY 2028 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2023 IPPS/LTCH PPS final rule (86 FR 49118), we established performance standards for the FY 2028 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in Table V.L.–10.

TABLE V.L.-10: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877260	0.893229
MORT-30-HF	0.885427	0.910649
MORT-30-PN (updated cohort)	0.831776	0.866166
MORT-30-COPD	0.913752	0.929652
MORT-30-CABG	0.971052	0.980570
COMP-HIP-KNEE*	0.029758	0.022002
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included in the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49106 through 49110), which excludes patients diagnosed with COVID-19 and risk-adjusts for history of COVID-19 for these measures.

d. Previously Established Performance Standards for Certain Measures for the FY 2029 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59091 through 59092), we established performance standards for the FY 2029 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in Table V.L.–11.

TABLE V.L.-11: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.874856	0.893101
MORT-30-HF	0.880089	0.9072
MORT-30-PN (updated cohort)	0.814736	0.853996
MORT-30-COPD	0.905916	0.924829
MORT-30-CABG	0.971027	0.979822
COMP-HIP-KNEE*	0.025024	0.018708
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49106 through 49110), which excludes patients diagnosed with COVID-19 and risk adjusts for history of COVID-19 for these measures.

e. Newly Established Performance Standards for Certain Measures for the FY 2030 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB Hospital) for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2030 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.L.–12.

TABLE V.L.-12: NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2030 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.873975	0.89371
MORT-30-HF	0.878881	0.90929
MORT-30-PN (updated cohort)	0.81782	0.858688
MORT-30-COPD	0.903404	0.924332
MORT-30-CABG	0.979681	0.986225
COMP-HIP-KNEE*	0.028252	0.019993
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49106 through 49110), which excludes patients diagnosed with COVID-19 and risk adjusts for history of COVID-19 for these measures.

M. Hospital-Acquired Condition (HAC) Reduction Program

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50709) for a general overview of the HAC Reduction Program and a detailed discussion of the statutory basis for the Program. We also refer readers to 42 CFR 412.170 through 412.172 for codified HAC Reduction Program requirements.

2. Measures for FY 2025 and Subsequent Years in the HAC Reduction Program

The previously finalized measures for the HAC Reduction Program are shown in table V.M.-01. Technical specifications for the CMS PSI 90 measure can be found on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC National Healthcare Safety Network (NHSN) HAI measures can be found at the CDC's NHSN website at *http://www.cdc.gov/nhsn/acute-care-hospital/index.html* and on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/hai/resources*. These web pages provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

TABLE V.M.-01: HAC REDUCTION PROGRAM MEASURES FOR FY 2025 AND SUBSEQUENT YEARS

Short Name	Measure Name	Consensus-Based Entity (CBE)#
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

We are not making any proposals or updates for the HAC Reduction Program in this proposed rule. We refer readers to section I.G.9. of Appendix A of this proposed rule for an updated estimate of the impact of the Program policies on the proportion of hospitals in the worst performing quartile of the Total HAC Scores for the FY 2025 HAC Reduction Program.

N. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260). In the preamble of this proposed rule, we summarize the status of the demonstration program, and the current methodologies for implementation and calculating budget neutrality.

We are also proposing the amount to be applied to the national IPPS payment rates to account for the costs of the demonstration in FY 2025, and, in addition, we are proposing to include the reconciled amount of demonstration costs for FY 2019 in the FY 2025 IPPS/LTCH final rule. We expect all finalized cost reports for this earlier year to be available by that time.

2. Background

Section 410A(a) of the MMA (Pub. L. 108–173) required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Our policy for implementing the 5-year extension period authorized by the CAA, 2021 (Pub. L. 116–260) follows upon the previous extensions under the Affordable Care Act (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255). Section 410A of the MMA (Pub. L. 108–173) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. In addition, the Affordable Care Act (Pub. L. 111–148) limited the number of hospitals participating to no more than 30. Section 15003 of the Cures Act (Pub. L. 114–255) required a 10-year extension period in place of the 5-year extension period under the Affordable Care Act (Pub. L. 111–148), thereby extending the demonstration for another 5 years. Section 128 of CAA, 2021 (Pub. L. 116–260), in turn, revised the statute to indicate a 15-year extension period, instead of the 10-year extension period mandated by the Cures Act (Pub. L. 114–255).

Please refer to the FY 2023 IPPS proposed and final rules (87 FR 28454 through 28458 and 87 FR 49138 through 49142, respectively) for an account of hospitals entering into and withdrawing from the demonstration with these re-authorizations. There are currently 23 hospitals participating in the demonstration.

2. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of the MMA (Pub. L. 108–173) requires that, in conducting the demonstration program under this section, the Secretary shall ensure that

the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays will produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (We applied a different methodology for FY 2017, with the demonstration expected to end prior to the Cures Act extension.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

We resumed this methodology of offsetting demonstration costs against the national payment rates in the IPPS final rules from FY 2018 through FY 2024. Please see the FY 2024 IPPS final rule for an account of how we applied the budget neutrality requirement for these fiscal years (88 FR 59114 through 59116).

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year.

We note that we have calculated this difference for FYs 2005 through 2018 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by CAA, 2021

For the most-recently enacted extension period, under the CAA, 2021, we have continued upon the general budget neutrality methodology used in previous years, as described above in the citations to earlier IPPS final rules. In this proposed rule, we outline the methodology to be used for determining the offset to the national IPPS payment rates for FY 2025.

(1) Methodology for Estimating Demonstration Costs for FY 2025

Consistent with the general methodology from previous years, we are estimating the costs of the demonstration for the upcoming fiscal year, and proposing to incorporate this estimate into the budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2025. We are conducting this estimate for FY 2025 based on the 23 currently participating hospitals. The methodology for calculating this amount for FY 2025 proceeds according to the following steps:

Step 1: For each of these 23 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2022. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 23 hospitals eligible to participate during FY 2025.

Then, we multiply this amount by the FYs 2023, 2024, and 2025 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (We are using the proposed market basket percentage increase for FY 2025, which can be found at section V.B.1. of the preamble to this proposed rule). The result for the 23 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2025.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2023 through 2025 to the applicable estimated reasonable cost amount (previously described) to model the estimated FY 2025 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2025 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2023, 2024, and 2025 IPPS applicable percentage increases. (For FY 2025, we are using the proposed applicable percentage increase, per section V.B.1. of the preamble of this proposed rule). This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost

amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 23 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2025.

For this proposed rule, the resulting amount is $49,522,206, to be incorporated into the budget neutrality offset adjustment for FY 2025. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. If updated data become available prior to the final rule, we will use them as appropriate to estimate the costs for the demonstration program for FY 2025 in accordance with our methodology for determining the budget neutrality estimate. We will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration.

(2) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2018 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

At this time, for the FY 2025 proposed rule, not all of the finalized cost reports are available for the 26 hospitals that completed cost report periods beginning in FY 2019 under the demonstration payment methodology. We expect all of these finalized cost reports to be available by the time of the final rule, and thus we are proposing to include the difference between the actual cost of the demonstration for FY 2019 as determined from finalized cost reports within the budget neutrality offset amount in the FY 2025 final rule.

(3) Total Proposed Budget Neutrality Offset Amount for FY 2025

Therefore, for this FY 2025 IPPS/LTCH PPS proposed rule, the proposed budget neutrality offset amount for FY 2025 is the amount determined under section X.2.c.(2) of the preamble of this proposed rule, representing the difference applicable to FY 2025 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 23 hospitals eligible to participate in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $49,522,206.

However, we note, that the overall amount might change if there are any revisions prior to the final rule to the data used to formulate this estimate. We also expect to revise the budget neutrality offset amount upon calculating the actual costs of the demonstration for FY 2019, after receiving all of the finalized cost reports for that fiscal year.

VI. Proposed Changes to the IPPS for Capital Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient

hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2025

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2025 is discussed in section III. of the Addendum to this FY 2025 IPPS/LTCH PPS proposed rule.

VII. Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2025

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs.

Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating market basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating market basket to a 2018 base year. Therefore, we used the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years.

For this FY 2025 IPPS/LTCH PPS proposed rule, based on IGI's 2023 fourth quarter forecast, we estimate that the 2018-based IPPS operating market basket percentage increase for FY 2025 is 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2025 rate-of-increase percentage that will be applied to the FY 2024 target amounts in order to calculate the FY 2025 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the FY 2025 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2025.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2025, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the

regulations, for cost reporting periods beginning during FY 2025, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is estimated to be the percentage increase in the 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2025 is 3.0 percent, which is based on IGI's fourth quarter 2023 forecast. Furthermore, we are proposing that if more recent data become available for the FY 2025 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2025.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this proposed rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 591222), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the proposed rule as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section of the proposed rule as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022.

As described in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2024 IPPS/LTCH PPS final rule. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, three CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. CMS Intervention Payment and Payment Waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site for Medicare telehealth services. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS reimburses the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS does not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies that the payment for a telehealth service furnished by a distant site practitioner is the same as it would be if the service had been furnished in-person. CMS modifies the payment amount specified for telehealth services under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(i)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a), 42 CFR 485.645(a)(2), and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating

CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule, because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy that in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We explained our belief that this policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we finalized a policy in the FY 2023 IPPS/LTCH PPS final rule that we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

e. Policies for Implementing the 5-Year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

f. Total Budget Neutrality Offset Amount for FY 2025

At this time, for the FY 2025 IPPS/LTCH PPS proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Therefore, we do not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2025. This policy would have no impact for any national payment system for FY 2025.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2025

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register** (67 FR 55954), we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA. For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to (82 FR 38299).)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-

percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

i. General

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

ii. Proposed Technical Clarification

As explained more fully previously, LTCHs are required to have an average length of stay (ALOS) of greater than 25 days. Prior to a hospital being classified as an LTCH, the hospital must first participate in Medicare as a hospital (typically a hospital paid under the IPPS) during which time ALOS data is gathered. This data is used to determine whether the hospital has an ALOS of greater than 25 days, which is required to be classified as an LTCH. We generally refer to the period during which a hospital seeks to establish the required ALOS as a ''qualifying period.'' The qualifying period is the 6-month period immediately preceding the hospital's conversion to an LTCH, and it has been our policy that the requisite ALOS must be demonstrated based on patient data from at least 5 consecutive months of this period. For example, for a hospital seeking to become an LTCH effective January 1, 2025, the qualifying period would be July 1, 2024 through December 31, 2024 (that is, the 6 months immediately preceding the conversion to an LTCH). In order for the hospital to convert to an LTCH, the ALOS must be demonstrated for a period of at least 5 consecutive months (for example, July 1, 2024 through November 30, 2024 or July 15, 2024 to December 14, 2024) of the 6 month qualifying period.

It has been our general policy to allow a hospital to be classified as an LTCH after only the 6-month qualifying period (as opposed to requiring the completion of the more typical 12-month cost reporting period). We have also referred to the ability of a hospital to be classified as an LTCH after a 6-month qualifying period in preamble previously (73 FR 29705), and the Provider Reimbursement Manual at 3001.4 refers to using data from a 6-month period for hospitals which have not yet filed a cost report. However, our regulations have never explicitly articulated how the qualifying period policy applies to a hospital seeking classification as an LTCH. Therefore, we are proposing to revise our regulations at 42 CFR 412.23(e)(4) to explicitly state that a hospital that seeks to be classified as an LTCH may do so after completion of a 6-month qualifying period, provided that the hospital demonstrates an average length of stay (calculated under our existing regulations) of greater than 25 days during at least five consecutive months of the 6-month qualifying period (which is the same timeframe as the ''cure period'' for existing LTCHs). Specifically, we are proposing to add new paragraph § 412.23(e)(4)(iv) to explain the qualifying period for hospitals seeking LTCH classification.

Further, we are proposing to revise certain paragraphs and reorder certain paragraphs in § 412.23(e) to improve the clarity of the regulation by clarifying how provisions apply to existing LTCHs and which provisions apply to hospitals seeking classification as an LTCH. First, we are proposing to revise paragraph § 412.23(e)(3)(i) to incorporate a reference that includes new subparagraphs § 412.23(e)(4)(iv) and (e)(4)(v). Second, we are proposing to revise paragraph § 412.23(e)(3)(iii) to clarify that it applies in cases of hospitals that have already obtained LTCH classification when the LTCH would not otherwise maintain an average Medicare inpatient length of stay of greater than 25 days. Third, we are proposing to reserve § 412.23(e)(3)(iv) and move that text to new (e)(4)(v) in order to clarify that this regulation applies to hospitals seeking new LTCH classification. Fourth, we are proposing to revise § 412.23(e)(4) to clarify that the provisions of paragraph (e)(3), with the exception of subparagraphs (e)(3)(iii) and (v) apply to hospitals seeking new LTCH classification. Fifth, we are proposing to revise paragraph § 412.23(e)(4)(i) to reflect the addition of new § 412.23(e)(4)(iv) and (e)(4)(v) and clarify existing regulatory language.

We note that none of these proposed revisions reflect a change to our existing policy; instead, we believe these revisions will improve the clarity of the regulatory text and better reflect our existing policy.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3021 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will

only pay for services. furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2025

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2025, there would be 773 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 standard, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162.

Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare Administrative Contractors (MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2025

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2024 through September 30, 2025 (FY 2025) consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2025 are the same as the MS–DRGs being proposed for use under the IPPS for FY 2025. In addition, because the proposed MS–LTC–DRGs for FY 2025 are the same as the proposed MS–DRGs for FY 2025, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 42, as discussed in section II.E. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2025.

3. Proposed Development of the FY 2025 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs. We also made a modification in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH

PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). We also adopted, beginning in FY 2023, a 10-percent cap policy on the reduction in a MS–LTC–DRG's relative weight in a given year. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). For details on our adoption of the 10-percent cap policy, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49152 through 49154).)

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our proposed methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our proposed methodology). For FY 2025, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2025 MS–LTC–DRG relative weights.

b. Development of the MS–LTC–DRG Relative Weights for FY 2025

In this section, we present our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2025. We first list and provide a brief description of our proposed steps for determining the FY 2025 MS–LTC–DRG relative weights. We then, later in this section, discuss in greater detail each step. We note that, as we did in FY 2024, we are proposing to use our historical relative weight methodology as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a ten percent cap as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162).

- Step 1—Prepare data for MS–LTC–DRG relative weight calculation. In this step, we select and group the applicable claims data used in the development of the proposed MS–LTC–DRG relative weights.
- Step 2—Remove cases with a length of stay of 7 days or less. In this step, we trim the applicable claims data to remove cases with a length of stay of 7 days or less.
- Step 3—Establish low-volume MS–LTC–DRG quintiles. In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with fewer than 25 cases).
- Step 4—Remove statistical outliers. In this step, we trim the applicable claims data to remove statistical outlier cases.
- Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs). In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases.
- Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology. In this step, we use our established hospital-specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights.
- Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights. In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity.
- Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases. In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight.
- Step 9—Budget neutralize the uncapped relative weights. In this step, to ensure budget neutrality in the annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS–LTC–DRG classifications and relative weights.
- Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights. In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.
- Step 11—Budget neutralize the application of the 10-percent cap policy. In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

We next describe each of the 11 proposed steps for calculating the proposed FY 2025 MS–LTC–DRG relative weights in greater detail.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

For this FY 2025 IPPS/LTCH PPS proposed rule, we obtained total charges from FY 2023 Medicare LTCH claims data from the December 2023 update of the FY 2023 MedPAR file and used proposed Version 42 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if better data become available, we would use those data and the finalized Version 42 of the GROUPER in establishing the FY 2025 MS–LTC–DRG relative weights in the final rule.

To calculate the FY 2025 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the December 2023 update of the FY 2023 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2023 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that

subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2023 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, all LTCH PPS cases in FY 2023 with admission dates on or before the PHE expiration date were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. However, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2025 (including MS–LTC–DRG relative weights), we used FY 2023 cases that meet the statutory patient criteria without consideration to how those cases were paid in FY 2023.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed the abnormal charging practices of an LTCH (CCN 312024) in FY 2021 that led to the LTCH receiving an excessive amount of high cost outlier payments. In that rule, we stated our belief, based on information we received from the provider, that these abnormal charging practices would not persist into FY 2023. Therefore, we did not include their cases in our model for determining the FY 2023 outlier fixed-loss amount. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59127 through 59128), we stated that the FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. Therefore, we removed claims from CCN 312024 when determining the FY 2024 MS–LTC–DRG relative weights and from all other FY 2024 ratesetting calculations, including the calculation of the area wage level adjustment budget neutrality factor and the fixed-loss amount for LTCH PPS standard Federal payment rate cases. Given recent actions by the Department of Justice regarding CCN 312024 (see *https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related*), we are proposing to again remove claims from CCN 312024 when determining the FY 2025 MS–LTC–DRG relative weights and all other FY 2025 ratesetting calculations, including the calculation of the area wage level adjustment budget neutrality factor and the fixed-loss amount for LTCH PPS standard Federal payment rate cases.

In summary, in general, we identified the claims data used in the development of the FY 2025 MS–LTC–DRG relative weights in this proposed rule by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all-inclusive rate providers reported in the December 2023 update of the FY 2023 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2023 update of the FY 2023 MedPAR file, but had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. We also removed all claims from CCN 312024.

We used the remaining data (that is, the applicable LTCH data) in the subsequent proposed steps to calculate the proposed MS–LTC–DRG relative weights for FY 2025.

Step 2—Remove cases with a length of stay of 7 days or less.

The next step in our proposed calculation of the proposed FY 2025 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2025 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2025 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish low-volume MS–LTC–DRG quintiles.

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)).

In this proposed rule, based on the best available data (that is, the December 2023 update of the FY 2023 MedPAR file), we identified 236 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5. The quintiles each contained at least 47 MS–LTC–DRGs (236/5 = 47 with a remainder of 1). We are proposing to employ our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG. In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles

results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our proposed methodology.

To determine the FY 2025 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our proposed methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

For this proposed rule, we are providing the list of the composition of the proposed low-volume quintiles for low-volume MS–LTC–DRGs in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

Step 4—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2025 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).

As the next step in the proposed calculation of the proposed FY 2025 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2025 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we propose to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative value methodology.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2025. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an

LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, we propose to calculate the proposed FY 2025 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Therefore, in accordance with our established methodology, for FY 2025, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our proposed methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the FY 2025 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, it's case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2025 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2025 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the December 2023 update of the FY 2023 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to cross-walk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same relative weight (and

average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this proposed rule).

Of the 773 proposed MS–LTC–DRGs for FY 2025, we identified 425 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 425 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 397 MS–LTC–DRGs that for which, we are proposing to assign a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, 425 − 11 − 2 − 15 = 397). We are proposing to assign relative weights to each of the 397 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 348 (773 − 425 = 348) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2023 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 348 MS–LTC–DRGs to which we cross-walked each of the 397 ''no-volume'' MS–LTC–DRGs.) Then, in general, we are proposing to assign the 397 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the December 2023 update of the FY 2023 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2025, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2025. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2025. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this proposed rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2025 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the FY 2025 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2023 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that proposed MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we are proposing to assign the same relative weight (and average length of stay) of proposed MS–LTC–DRG 064 of 1.3009 for FY 2025 to proposed MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, we are proposing to use the best available claims data to identify the trimmed applicable LTCH cases from which we determine the relative weights in the final rule.

For FY 2025, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas and Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas and Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for

the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedures with Principal Diagnosis of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Intellectual Disability); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol, Drug Abuse or Dependence, Left AMA); MS–LTC–DRG 895 (Alcohol, Drug Abuse or Dependence with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are proposing to establish a relative weight of 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2025, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Budget neutralize the uncapped relative weights.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to continue to apply budget neutrality adjustments in determining the proposed FY 2025 MS–LTC–DRG relative weights so that our proposed update of the MS–LTC–DRG classifications and relative weights for FY 2025 are made in a budget neutral manner. For FY 2025, we are proposing to apply two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the proposed update of the MS–LTC–DRG classifications and relative weights prior to the application of the ten-percent cap. In steps 10 and 11, we describe the application of the 10-percent cap policy (step 10) and the determination of the proposed budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this proposed rule, to ensure budget neutrality for the proposed update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2025, we calculated and applied a proposed normalization factor to the recalibrated relative weights (the result of Steps 1 through 8 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2025, we propose to use the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2023 MedPAR file) and group them using the proposed FY 2025 GROUPER (that is, Version 42 for FY 2025) and the proposed recalibrated FY 2025 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 8 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2024 GROUPER (Version 41) and FY 2024 MS–LTC–DRG relative weights in Table 11 of the FY 2024 IPPS/LTCH PPS final rule and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2024 (determined in Step 1.b.) by the average case-mix index for FY 2025 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2025, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the proposed normalization factor of 1.27356 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a proposed budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration. That is, for this proposed rule, for FY 2025, we propose to determine the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2025 and proposed GROUPER Version 42; (2.b.) simulate estimated total FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2024 GROUPER (Version 41) and the FY 2024 MS–LTC–DRG relative weights in Table 11 of the FY 2024 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2025 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a proposed budget neutrality factor of 0.988292 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.

To mitigate the financial impacts of significant year-to-year reductions in MS–LTC–DRGs relative weights, beginning in FY 2023, we adopted a policy that applies, in a budget neutral manner, a 10-percent cap on annual relative weight decreases for MS–LTC–

DRGs with at least 25 applicable LTCH cases (§ 412.515(b)). Under this policy, in cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year. We refer readers to section VIII.B.3.b. of the preamble of the FY 2023 IPPS/LTCH PPS final rule with comment period for a detailed discussion on the adoption of the 10-percent cap policy (87 FR 49152 through 49154).

Applying the 10-percent cap to MS–LTC–DRGs with 25 or more cases results in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. For this proposed rule, in cases where the relative weight for a MS–LTC–DRG with 25 or more applicable LTCH cases would decrease by more than 10-percent in FY 2025 relative to FY 2024, we are proposing to limit the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the proposed low-volume MS–LTC–DRGs identified in Step 3 or the proposed no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each proposed FY 2025 MS–LTC–DRG with 25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2025 relative weight (after application of the proposed normalization and proposed budget neutrality factors determined in Step 9), to its FY 2024 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2025 relative weight would otherwise have declined more than 10 percent, we established a proposed capped FY 2025 MS–LTC–DRG relative weight that would be equal to 90 percent of that MS–LTC–DRG's FY 2024 relative weight (that is, we set the proposed FY 2025 relative weight equal to the FY 2024 weight × 0.90).

In section II.E. of the preamble of this proposed rule, we discuss our proposed changes to the MS–DRGs, and by extension the MS–LTC–DRGs, for FY 2025. As discussed previously, under our current policy, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs. We are not proposing any changes to this policy for FY 2025, and as such any proposed new or renumbered MS–LTC–DRGs for FY 2025 would not be eligible for the 10-percent cap.

Step 11—Budget neutralize application of the 10-percent cap policy.

Under the requirement at existing § 412.517(b) that aggregate LTCH PPS payments will be unaffected by annual changes to the MS–LTC–DRG classifications and relative weights, consistent with our established methodology, we are proposing to continue to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we are proposing to determine the proposed budget neutrality adjustment factor for the 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2025 (determined in Step 10) and proposed GROUPER Version 42; (b) simulate estimated total FY 2025 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2025 (determined in Step 9) and proposed GROUPER Version 42; and (c) calculate the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the proposed FY 2025 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a proposed budget neutrality factor of 0.9946599 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, proposed geometric mean length of stay, and proposed five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2025. We also are making available on the website the proposed MS–LTC–DRG relative weights prior to the application of the 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding proposed cap budget neutrality factor.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2025

1. Overview of Development of the Proposed LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2025, that is, effective for LTCH discharges occurring on or after October 1, 2024, through September 30, 2025. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003 through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2025 IPPS/LTCH PPS proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2025.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2025 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2025 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2025 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this

proposed rule). We are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2025 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

2. Proposed FY 2025 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). As discussed in section VIII.D. of the preamble of this proposed rule, we are proposing to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2025

As previously noted, for FY 2025, we are proposing to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year. The proposed 2022-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of LTCHs. As described in more detail in section VIII.D.1 of the preamble of this proposed rule, we are proposing to use data from cost reporting periods beginning on and after April 1, 2021, and prior to April 1, 2022 because these data reflect the most recent information that are most representative of FY 2022. We believe that the proposed 2022-based LTCH market basket appropriately reflects the cost structure of LTCHs, as discussed in greater detail in section VIII.D. of the preamble of this proposed rule. In this proposed rule, we are proposing to use the proposed 2022-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2025.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.* Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2025.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, requires that a 2.0 percentage points reduction be applied to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than

such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section IX. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2025

Consistent with our historical practice, we estimate the market basket percentage increase and the productivity adjustment based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's fourth quarter 2023 forecast, the proposed FY 2025 market basket percentage increase for the LTCH PPS using the proposed 2022-based LTCH market basket is 3.2 percent. The proposed productivity adjustment for FY 2025 based on IGI's fourth quarter 2023 forecast is 0.4 percentage point.

For FY 2025, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the FY 2025 market basket percentage increase by the FY 2025 productivity adjustment. To determine the proposed market basket update for LTCHs for FY 2025 we subtracted the proposed FY 2025 productivity adjustment from the proposed FY 2025 market basket percentage increase. (For additional details on our established methodology for adjusting the market basket percentage increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).) In addition, for FY 2025, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points.

In this FY 2025 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2025 market basket percentage increase of 3.2 percent (based on IGI's fourth quarter 2023 forecast of the proposed 2022-based LTCH market basket) by the proposed FY 2025 productivity adjustment of 0.4 percentage point (based on IGI's fourth quarter 2023 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2025 of 2.8 percent (that is, the LTCH PPS market basket increase of 3.2 percent less the productivity adjustment of 0.4 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.8 percent (that is, the proposed 2.8 percent LTCH market basket update minus 2.0 percentage points) for FY 2025 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we are proposing to use a more recent estimate of the market basket percentage increase and the productivity adjustment, if appropriate, to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2025 in the final rule. We note that, consistent with historical practice, we are also proposing to adjust the FY 2025 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).

D. Proposed Rebasing of the LTCH Market Basket

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the ''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Since the LTCH PPS inception, the market basket used to update LTCH PPS payments has been rebased and revised to reflect more recent data. We last rebased and revised the market basket applicable to the LTCH PPS in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926), where we adopted a 2017-based LTCH market basket. References to the historical market baskets used to update LTCH PPS payments are listed in the FY 2021 LTCH PPS final rule (85 FR 58909 through 58910).

For this FY 2025 IPPS/LTCH proposed rule, we propose to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year, which would maintain our historical frequency of rebasing the market basket every 4 years. The proposed 2022-based LTCH market basket is primarily based on Medicare cost report data for LTCHs for FY 2022, specifically for cost reporting periods beginning on and after April 1, 2021, and prior to April 1, 2022. For the 2017-based LTCH market, we used Medicare cost report data for LTCHs from cost reporting periods beginning on and after October 1, 2016, and before October 1, 2017, or reports that began in FY 2017. The majority of LTCHs have a cost report begin date of September 1 and so those LTCHs with a cost report begin date of September 1, 2021 have the majority of their expenses occurring in the FY 2022 time period. We are proposing to use data from cost reporting periods beginning on and after April 1, 2021, and prior to April 1, 2022 because these data reflect the most recent Medicare cost report data for LTCHs at the time of rulemaking where the majority of their costs are occurring in FY 2022 while still maintaining our historical frequency of rebasing the market basket every 4 years.

We are unable to use data from the FY 2022 HCRIS file, which reflects cost reporting periods beginning on and after October 1, 2021 and prior to September 30, 2022, as most reporters have a begin date of September 1, so the dataset in the file is not yet complete. In the interest of utilizing the most recent, complete data available, we are proposing to combine data from multiple HCRIS files to obtain a 2022 base year. We are proposing to use a composite timeframe of cost reporting periods beginning on and after April 1, 2021 and prior to April 1, 2022, because

April 1 reflects the middle of the fiscal year and this timeframe would allow data from 2022 to be included in this rebasing. Using this proposed method, the weighted average of costs occurring in FY 2022 (accounting for the distribution of providers by Medicare cost report begin date) is 82 percent. Therefore, we believe our proposed methodology of using Medicare cost report data based on cost reporting periods beginning on or after April 1, 2021 and prior to April 1, 2022 reflects the most recent information that is most representative of FY 2022.

As described in the FY 2023 IPPS/LTCH final rule (87 FR 49164 through 49165), we received comments on the FY 2023 IPPS/LTCH PPS proposed rule where stakeholders expressed concern that the proposed market basket update was inadequate relative to input price inflation experienced by LTCHs, particularly as a result of the COVID–19 PHE. These commenters stated that the PHE, along with inflation, has significantly driven up operating costs. Specifically, some commenters noted changes to the labor markets that led to the use of more contract labor. As described in more detail later in this section, we verified this trend when analyzing the Medicare cost reports submitted by LTCHs through 2022. Therefore, we believe it is appropriate to incorporate more recent data to reflect updated cost structures for LTCHs, and so we propose to use 2022 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for developing the proposed LTCH market basket at the time of this rulemaking. Given the recent trends in the major cost weights derived from the Medicare cost report data as discussed later in this section, we will continue to monitor these data going forward and any additional changes to the LTCH market basket will be proposed in future rulemaking.

In the following discussion, we provide an overview of the proposed LTCH market basket, describe the proposed methodologies for developing the operating and capital portions of the proposed 2022-based LTCH market basket, and provide information on the proposed price proxies. Then, we present the proposed FY 2025 market basket update and labor-related share based on the proposed 2022-based LTCH market basket.

2. Overview of the Proposed 2022-Based LTCH Market Basket

Similar to the 2017-based LTCH market basket, the proposed 2022-based LTCH market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time relative to the base period are not measured. The index itself is constructed using three steps. First, a base period is selected (in this proposed rule, we propose to use 2022 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase to furnish inpatient care between base periods.

3. Development of the Proposed 2022-Based LTCH Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed in this section of this rule, for deriving the proposed 2022-based LTCH market basket.

a. Use of Medicare Cost Report Data

The major types of costs underlying the proposed 2022-based LTCH market basket are derived from the Medicare cost reports (CMS Form 2552–10, OMB Control Number 0938–0050) for LTCHs. Specifically, we use the Medicare cost reports for seven specific costs: Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office/Related Organization Contract Labor, and Capital. A residual category is then estimated and reflects all remaining costs not captured in the seven types of costs identified previously. The 2017-based LTCH market basket similarly used the Medicare cost reports.

Medicare cost report data include costs for all patients (including but not limited to those covered by Medicare, Medicaid, and private insurance). Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries and are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we propose to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10, OMB Control Number 0938–0050) Worksheet S–3, Part I, line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs associated with Medicare covered days as our proposed edit excludes those LTCHs that had an average total facility LOS that were notably different than the average Medicare LOS. For the 2017-based LTCH market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital. Based on our analysis of the 2022 Medicare cost reports, for the proposed 2022-based LTCH market basket, we propose to again use the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility

average LOS for the hospital. The universe of LTCHs had an average Medicare LOS of 26 days, an average total facility LOS of 35 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 34 percent in 2022. Applying the proposed trim excludes 11 percent of LTCH providers and results in a subset of LTCH Medicare cost reports with an average Medicare LOS of 26 days, average facility LOS of 30 days, and aggregate Medicare utilization (based on days) of 40 percent. The 11 percent of providers that are excluded had an average Medicare LOS of 29 days, average facility LOS of 71 days, and aggregate Medicare utilization of 14 percent.

We are proposing to use the cost reports for LTCHs that meet this requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital) for the market basket. Also, as described in section VIII.D.3.d. of the preamble of this proposed rule, and as done for the 2017-based LTCH market basket, we are also proposing to use the Medicare cost report data to calculate the detailed capital cost weights for the Depreciation, Interest, Lease, and Other Capital-Related cost categories.

(1) Wages and Salaries Costs

We propose to derive Wages and Salaries costs as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, column 1. Because overhead salary costs are attributable to the entire LTCH, we propose to only include the proportion attributable to the Medicare allowable cost centers. For the 2022-based LTCH market basket, we propose that routine and ancillary Wages and Salaries costs would be equal to salary costs as reported on Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93. Then, we are proposing to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers. We propose to first calculate overhead salaries as the sum of Worksheet A, column 1, lines 4 through 18. We then calculate the ''Medicare allowable ratio'' equal to routine and ancillary Wages and Salaries divided by total non-overhead salaries (Worksheet A, column 1, line 200 less overhead salaries). We propose to multiply this Medicare allowable ratio by overhead salaries to determine the overhead salaries attributed to Medicare allowable cost centers. The sum of routine salaries, ancillary salaries, and the estimated Medicare allowable portion of overhead salaries represent Wages and Salaries costs. A similar methodology was used to derive Wages and Salaries costs in the 2017-based LTCH market basket.

(2) Employee Benefits Costs

Similar to the 2017-based LTCH market basket, we propose to calculate Employee Benefits costs using data from Worksheet S–3, part II, column 4, lines 17, 18, 20, and 22. The completion of Worksheet S–3, part II is only required for IPPS hospitals. For 2022, we found that approximately 42 percent of LTCHs voluntarily reported the Employee Benefits data, which has increased from the approximately 20 percent of LTCHs that reported these data that were used for the 2017-based LTCH market basket. Our analysis of the Worksheet S–3, part II data submitted by these LTCHs indicates that we continue to have a large enough sample to enable us to produce a reasonable Employee Benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (such as by type of ownership—nonprofit, for-profit, and government—and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we propose to use Worksheet S–3, part II data (as was done for the 2017-based LTCH market basket) to calculate the Employee Benefits cost weight in the proposed 2022-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552–10, OMB Control Number 0938–0050, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part V, which is applicable to LTCHs. However, approximately 12 percent of LTCHs reported data on Worksheet S–3, part V for 2022, which has fallen since 2017 when roughly 17 percent of LTCHs reported these data. Because a greater percentage of LTCHs continue to report data on Worksheet S–3, part II than Worksheet S–3, part V, we are not proposing to use the Employee Benefits and Contract Labor data reported on Worksheet S–3, part V to calculate the Employee Benefits and Contract Labor cost weights in the proposed 2022-based LTCH market basket. We continue to encourage all providers to report Employee Benefits and Contract Labor data on Worksheet S–3, part V.

(3) Contract Labor Costs

Contract Labor costs reported on the Medicare cost reports are primarily associated with direct patient care services. Contract Labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this section of this proposed rule. Approximately 40 percent of LTCHs voluntarily reported Contract Labor costs on Worksheet S–3, part II, which was similar to the percentage obtained from 2017 Medicare cost reports.

As was done for the 2017-based LTCH market basket, we propose to derive the Contract Labor costs for the proposed 2022-based LTCH market basket using voluntarily reported data from Worksheet S–3, part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a representative Contract Labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs by region, the recalculation did not have a material effect on the resulting cost weight. Therefore, we propose to use data from Worksheet S–3, part II, column 4, lines 11 and 13 to calculate the Contract Labor cost weight in the proposed 2022-based LTCH market basket.

(4) Pharmaceuticals Costs

We propose to calculate Pharmaceuticals costs using non-salary costs reported for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73). We propose to calculate these costs as Worksheet A, column 7, less Worksheet A, column 1 for each of these lines. A similar methodology was used for the 2017-based LTCH market basket.

(5) Professional Liability Insurance Costs

We propose that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S–2, part I, columns 1 through 3, line 118. A similar methodology was used for the 2017-based LTCH market basket.

(6) Home Office/Related Organization Contract Labor Costs

We propose to calculate the Home Office/Related Organization Contract Labor costs using data reported on Worksheet S–3, part II, column 4, lines 1401, 1402, 2550, and 2551 for those LTCH providers reporting total salaries on Worksheet S–3, part II, line 1. A

similar methodology was used for the 2017-based LTCH market basket.

(7) Capital Costs

We propose that Capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91 and 93. A similar methodology was used for the 2017–based LTCH market basket.

b. Final Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to trim the data for outliers. For each of the seven major cost categories, we are first proposing to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of LTCH providers. For the 2022–based LTCH market basket (similar to the approach used for the 2017–based LTCH market basket), we propose that total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

For the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital cost weights, after excluding cost weights that are less than or equal to zero, we propose to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider specific derived cost weights to ensure the exclusion of outliers. We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2017–based LTCH market basket. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We are proposing to divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2022–based LTCH market basket for the given category. This trimming process is done for each cost weight separately.

For the Home Office/Related Organization Contract Labor cost weight, we propose to apply a 1-percent top only trimming methodology. We believe, as the Medicare cost report data (Worksheet S–2, part I, line 140) indicate, that not all LTCHs have a home office. LTCHs without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, LTCHs without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All Other'' cost weight. We believe this 1-percent top-only trimming methodology is appropriate as it addresses outliers while allowing providers with zero Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation. If we applied both the top and bottom 5 percent trimming methodology, we would exclude providers who have zero Home Office/Related Organization Contract Labor costs.

Finally, we propose to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. We refer readers to Table EEEE 1 for the resulting proposed cost weights for these major cost categories.

TABLE VIII.D-01—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Major Cost Categories	Proposed 2022-Based LTCH Market Basket (Percent)	2017-Based LTCH Market Basket (Percent)
Wages and Salaries	42.7	42.6
Employee Benefits	6.5	6.2
Contract Labor	12.6	4.4
Professional Liability Insurance (Malpractice)	0.7	0.5
Pharmaceuticals	4.5	6.2
Home Office/Related Organization Contract Labor	3.7	1.9
Capital	8.5	9.9
All Other	20.8	28.3

The Wages and Salaries and Employee Benefits cost weights calculated from the Medicare cost reports for the proposed 2022–based LTCH market basket are similar to the Wages and Salaries and Employee Benefits cost weights for the 2017–based LTCH market basket. The proposed Contract Labor cost weight, however, is approximately 8 percentage points higher than the Contract Labor cost weight in the 2017–based LTCH market basket. The proposed 2022–based Pharmaceuticals and Capital cost weights are lower than the 2017–based LTCH market basket by 1.7 percentage points and 1.4 percentage points, respectively. The proposed 2022–based Home Office/Related Organization Contract Labor cost weight has increased by 1.8 percentage points compared to the 2017–based LTCH market basket.

As we did for the 2017–based LTCH market basket, we propose to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that Contract Labor costs are comprised of both Wages and Salaries and Employee Benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage is 87 percent. Therefore, we propose to allocate 87 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 13 percent to the Employee Benefits cost weight. We refer readers to Table EEEE 2 that shows the proposed Wages and Salaries and

Employee Benefits cost weights after Contract Labor cost weight allocation for both the proposed 2022–based LTCH market basket and the 2017–based LTCH market basket.

TABLE VIII.D-02 WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major Cost Categories	Proposed 2022-Based LTCH Market Basket	2017-Based LTCH Market Basket
Compensation	**61.8**	**53.2**
Wages and Salaries	53.6	46.4
Employee Benefits	8.2	6.8

After the allocation of the Contract Labor cost weight, the proposed 2022–based Wages and Salaries cost weight is 7.2 percentage points higher and the Employee Benefits cost weight is 1.4 percentage points higher, relative to the respective cost weights for the 2017–based LTCH market basket. As a result, in the proposed 2022–based LTCH market basket, the compensation cost weight is 8.6 percentage points higher than the Compensation cost weight for the 2017–based LTCH market basket.

c. Derivation of the Detailed Operating Cost Weights

To further divide the residual ''All Other'' cost weight estimated from the 2022 Medicare cost report data into more detailed cost categories, we propose to use the 2017 Benchmark I–O ''The Use Table (Supply-Use Framework)'' data for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following website: *https://www.bea.gov/industry/input-output-accounts-data.* For the 2017-based LTCH market basket, we used the 2012 Benchmark I–O data, the most recent data available at the time (85 FR 58913).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[181] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we propose to inflate the 2017 Benchmark I–O data forward to 2022 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data, and calculated the cost shares that each cost category represents using the inflated data. These resulting 2022 cost shares were applied to the residual ''All Other'' cost weight to obtain the detailed cost weights for the proposed 2022–based LTCH market basket. For example, the cost for Food: Direct Purchases represents 4.3 percent of the sum of the residual ''All Other'' 2017 Benchmark I–O Hospital Expenditures inflated to 2022. Therefore, the Food: Direct Purchases cost weight represents 4.3 percent of the proposed 2022–based LTCH market basket's residual ''All Other'' cost category (20.8 percent), yielding a ''final'' Food: Direct Purchases proposed cost weight of 0.9 percent in the proposed 2022–based LTCH market basket (0.043 × 20.8 percent = 0.9 percent).

Using this methodology, we propose to derive seventeen detailed LTCH market basket cost category weights within the proposed 2022–based LTCH market basket residual ''All Other'' cost weight (20.8 percent). These categories are: (1) Electricity and Other Non-Fuel Utilities; (2) Fuel: Oil and Gas; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other Nonlabor-Related Services. We note that these are the same categories as were used in the 2017–based LTCH market basket (with several cost categories being renamed for clarification purposes).

d. Derivation of the Detailed Capital Cost Weights

As described in section VIII.D.3.b. of the preamble of this proposed rule, we are proposing a Capital-Related cost weight of 8.5 percent in the proposed 2022–based LTCH market basket as calculated from the 2022 Medicare cost reports for LTCHs after applying the proposed trims as previously described. We propose to then separate this total Capital-Related cost weight into more detailed cost categories. Using Worksheet A–7 in the 2022 Medicare cost reports, we are able to group capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs, as shown in Table VIII.D–03, which is the same methodology used for the 2017–based LTCH market basket.

We also are proposing to allocate lease costs, which are 65 percent of total capital costs in the proposed 2022–based LTCH market basket, across each of the remaining detailed capital-related cost categories as was done in the 2017–based LTCH market basket. This would result in three primary capital-related cost categories in the proposed 2022 based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2022–based LTCH market basket. Rather, we propose to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done for the 2017–based LTCH market basket, we propose to assume that 10 percent of the lease costs represents

[181] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we are assuming that approximately 6.5 percent (65.0 percent × 0.1) of total capital-related costs represent lease costs attributable to overhead, and we propose to add this 6.5 percentage points to the 7.3 percent Other Capital-Related cost category weight. We are also proposing to distribute the remaining lease costs (58.5 percent, or 65.0 percent less 6.5 percentage points) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related cost category represented 21.0 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 21.0 percent is applied to the 58.5 percent of remaining lease expenses so that another 12.3 percentage points of lease expenses as a percent of total capital-related costs is allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight is 26.1 percent (7.3 percent + 6.5 percent + 12.3 percent). This is the same methodology used for the 2017–based LTCH market basket. The proposed allocation of these lease expenses are shown in Table VIII.D–03.

Finally, we propose to further divide the Depreciation and Interest cost categories. We propose to separate Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also propose to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For profit.

To disaggregate the Depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to Building and Fixed equipment, which we hereafter refer to as the ''fixed percentage.'' We propose to use depreciation and lease data from Worksheet A–7 of the 2022 Medicare cost reports, which is the same methodology used for the 2017–based LTCH market basket. Based on the 2022 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 39 percent of total depreciation costs, while depreciation costs for movable equipment account for 61 percent of total depreciation costs. As previously mentioned, we propose to allocate lease expenses among the Depreciation, Interest, and Other Capital-Related cost categories. We determined that leasing building and fixed equipment expenses account for 94 percent of total leasing expenses, while leasing movable equipment expenses account for 6 percent of total leasing expenses. We propose to sum the depreciation and leasing expenses for building and fixed equipment, as well as sum the depreciation and leasing expenses for movable equipment. This results in the proposed Building and Fixed Equipment Depreciation cost weight (after leasing costs are included) representing 78 percent of total depreciation costs and the Movable Equipment Depreciation cost weight (after leasing costs are included) representing 22 percent of total depreciation costs.

To disaggregate the Interest cost weight, we determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We propose to use interest costs data from Worksheet A–7 of the 2022 Medicare cost reports for LTCHs, which is the same methodology used for the 2017–based LTCH market basket. The nonprofit percentage determined using this method is 48 percent.

Table VIII.D–03 provides the proposed detailed capital cost shares obtained from the Medicare cost reports. Ultimately, if finalized, these detailed capital cost shares would be applied to the total Capital-Related cost weight determined in section VIII.D.3.b. of the preamble of this proposed rule to separate the total Capital-Related cost weight of 8.5 percent into more detailed cost categories and weights.

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TABLE VIII.D-03--CAPITAL COST SHARE COMPOSITION FOR THE PROPOSED 2022-BASED LTCH MARKET BASKET

	Capital Cost Share Composition Before Lease Expense Allocation (Percent)	Capital Cost Share Composition After Lease Expense Allocation (Percent)
Depreciation	**23**	**63**
Building and Fixed Equipment	18	49
Movable Equipment	5	14
Interest	**4**	**11**
Government/Nonprofit	2	5
For Profit	2	6
Lease	*65*	*N/A*
Other	**7**	**26**

Note: Detail may not add to total due to rounding.

e. Proposed 2022-Based LTCH Market Basket Cost Categories and Weights

Table VIII.D–04 shows the proposed cost categories and weights for the proposed 2022-based LTCH market basket compared to the 2017-based LTCH market basket.

TABLE VIII.D-04 **--PROPOSED 2022-BASED LTCH MARKET BASKET COST WEIGHTS COMPARED TO 2017-BASED LTCH MARKET BASKET COST WEIGHTS**

Cost Category	Proposed 2022-based LTCH Market Basket Cost Weight	2017-based LTCH Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**61.8**	**53.2**
Wages and Salaries	53.6	46.4
Employee Benefits	8.2	6.8
Utilities	**1.2**	**1.9**
Electricity and Other Non-Fuel Utilities	0.9	1.3
Fuel: Oil and Gas	0.3	0.6
Professional Liability Insurance	**0.7**	**0.5**
Malpractice	0.7	0.5
All Other Products and Services	**27.7**	**34.4**
All Other Products	**12.6**	**15.6**
Pharmaceuticals	4.5	6.2
Food: Direct Purchases	0.9	1.4
Food: Contract Services	1.4	1.6
Chemicals	0.4	0.5
Medical Instruments	3.4	3.6
Rubber and Plastics	0.5	0.5
Paper and Printing Products	0.6	0.8
Miscellaneous Products	1.0	1.1
All Other Services	**15.1**	**18.9**
Labor-Related Services	**6.2**	**9.7**
Professional Fees: Labor-Related	3.0	4.5
Administrative and Facilities Support Services	0.5	0.9
Installation, Maintenance, and Repair Services	1.0	2.1
All Other: Labor-Related Services	1.7	2.3
Nonlabor-Related Services	**8.9**	**9.1**
Professional Fees: Nonlabor-Related	6.1	5.9
Financial Services	1.2	1.2
Telephone Services	0.2	0.4
All Other: Nonlabor-Related Services	1.4	1.6
Capital-Related Costs	**8.5**	**9.9**
Depreciation	**5.3**	**5.5**
Building and Fixed Equipment	4.2	4.2
Movable Equipment	1.2	1.3
Interest Costs	**1.0**	**2.1**
Government/Nonprofit	0.5	0.4
For Profit	0.5	1.6
Other Capital-Related Costs	**2.2**	**2.3**

Note: Totals may not sum due to rounding.

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4. Selection of Proposed Price Proxies

After developing the proposed cost weights for the 2022-based LTCH market basket, we selected the most appropriate wage and price proxies currently available to represent the rate

of price change for each cost category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe that the CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table VIII.D–07 lists all price proxies that we propose to use for the 2022-based LTCH market basket. The next section of the rule contains a detailed explanation of the price proxies we are proposing for each cost category weight.

a. Price Proxies for the Operating Portion of the Proposed 2022-Based LTCH Market Basket

(1) Wages and Salaries

We propose to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU1026220000000I) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2017-based LTCH market basket (85 FR 58917).

(2) Employee Benefits

We propose to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for All Civilian workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2017-based LTCH market basket (85 FR 58917).

(3) Electricity and Other Non-Fuel Utilities

We propose to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2017-based LTCH market basket (85 FR 58917).

(4) Fuel: Oil and Gas

For the 2022-based LTCH market basket, we propose to use a blend of the PPI Industry for Petroleum Refineries (NAICS 3241), PPI for Other Petroleum and Coal Products (NAICS 32419) and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2017 Benchmark I–O data for NAICS 622000 Hospitals shows that Petroleum Refineries expenses account for approximately 86 percent, Other Petroleum and Coal Products expenses account for about 7 percent and Natural Gas expenses account for approximately 7 percent of Hospitals' (NAICS 622000) total Fuel: Oil and Gas expenses. Therefore, we propose to use a blend of 86 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110), 7 percent of the PPI for Other Petroleum and Coal Products (BLS series code PCU32419) and 7 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2017-based LTCH market basket used a 90/10 blend of the PPI Industry for Petroleum Refineries and PPI Commodity for Natural Gas, reflecting the 2012 I–O data (85 FR 58917). We believe that the three proposed price proxies are the most technically appropriate indices available to measure the price growth of the Fuel: Oil and Gas cost category in the 2022-based LTCH market basket.

(5) Professional Liability Insurance

We propose to continue to use the CMS Hospital Professional Liability Index as the price proxy for PLI costs in the proposed 2022-based LTCH market basket. To generate this index, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2017-based LTCH market basket (85 FR 58917).

(6) Pharmaceuticals

We propose to continue to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58917).

(7) Food: Direct Purchases

We propose to continue to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost

category. This is the same price proxy used in the 2017-based LTCH market basket (85 FR 58917).

(8) Food: Contract Purchases

We propose to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58917).

(9) Chemicals

Similar to the 2017-based LTCH market basket, we propose to use a four-part blended PPI as the proxy for the chemical cost category in the 2022-based LTCH market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). For the 2022-based LTCH market basket, we propose to derive the weights for the PPIs using the 2017 Benchmark I–O data. The 2017-based LTCH market basket used the 2012 Benchmark I–O data to derive the weights for the four PPIs (85 FR 58917 through 58918).

TABLE VIII.D-05: BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed 2022-based LTCH Chemical Weights (Percent)	2017-based LTCH Chemical Weights (Percent)	NAICS
PPI Industry for Industrial Gas Manufacturing	26	19	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing	10	13	325180
PPI Industry for Other Basic Organic Chemical Manufacturing	49	60	325190
PPI Industry for Other Miscellaneous Chemical Product Manufacturing	15	8	325998

(10) Medical Instruments

We propose to use a blended price proxy for the Medical Instruments category. The 2017 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112—Surgical and medical instrument manufacturing costs (approximately 64 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 36 percent). To proxy the price changes associated with NAICS 339112, we propose to use the PPI for Surgical and medical instruments (BLS series code WPU1562). This is the same price proxy we used in the 2017-based LTCH market basket. To proxy the price changes associated with NAICS 339113, we propose to use a 50/50 blend of the PPI for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571). We propose to include the latter price proxy as it would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2017 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by LTCHs. For the 2017-based LTCH market basket, we used a blend composed of 57 percent of the commodity-based PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562) and 43 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563) reflecting the 2012 Benchmark I–O data (85 FR 58918).

(11) Rubber and Plastics

We propose to continue to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(12) Paper and Printing Products

We are proposing to use a 61/39 blend of the PPI Commodity for Publications Printed Matter and Printing Material (BLS Series Code WPU094) and the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. The 2017 Benchmark I–O data shows that 61 percent of paper and printing expenses are for Printing (NAICS 323110) and the remaining expenses are for Paper manufacturing (NAICS 322). The 2017-based LTCH market basket (85 FR 58918) used the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) as this comprised the majority of expenses as reported in the 2012 Benchmark I–O data.

(13) Miscellaneous Products

We propose to continue to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(14) Professional Fees: Labor-Related

We propose to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(15) Administrative and Facilities Support Services

We propose to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(16) Installation, Maintenance, and Repair Services

We propose to continue to use the ECI for Total Compensation for All Civilian

workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(17) All Other: Labor-Related Services

We propose to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58918).

(18) Professional Fees: Nonlabor-Related

We propose to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58919).

(19) Financial Services

We propose to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58919).

(20) Telephone Services

We propose to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58919).

(21) All Other: Nonlabor-Related Services

We propose to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2017-based LTCH market basket (85 FR 58919).

b. Price Proxies for the Capital Portion of the Proposed 2022-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We propose to continue to use the same price proxies for the capital-related cost categories as were applied in the 2017-based LTCH market basket, which are provided in Table VIII.D–07 and described in this section of this rule. Specifically, we propose to proxy:

- Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).
- Depreciation: Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
- For-profit Interest cost category by the average yield of the iBoxx AAA Corporate Bond Yield index.
- Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest in order to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2017-based LTCH market basket and is described in section VIII.D.4.b.(2). of the preamble of this proposed rule.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2022-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We propose to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for LTCH capital-related costs. The capital-related component of the proposed 2022-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the proposed 2022-based LTCH market basket is the same as that used for the 2017-based LTCH market basket with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the previously mentioned components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA does provide a consistent database of total expenses from 1963 to 2020—the latest available data. Consequently, we propose to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We are also proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2020. We propose to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as previously determined. From these annual depreciation amounts we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe this information for all hospitals serves as a reasonable proxy for the pattern of depreciation for LTCHs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2022-based LTCH market basket. We propose to calculate the expected lives using Medicare cost report data for LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 16 years, and the average expected life of movable equipment to be equal to 9 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2017-based LTCH-specific market basket, we derived an expected average life of building and fixed equipment of 18 years and an expected average life of movable equipment of 9 years (85 FR 58920).

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. Then we calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we propose to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as previously provided. For the interest vintage weights, we propose to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we propose to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 16 years, and in the case of movable equipment, 9 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2020 back to 1964. These data allow us to derive forty-two 16-year periods of capital-related purchases for building and fixed equipment and interest, and forty-nine 9-year periods of capital-related purchases for movable equipment. For each 16-year period for building and fixed equipment and interest, or 9-year period for movable equipment, we propose to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 16-year or 9-year period. This calculation is done for each year in the 16-year or 9-year period and for each of the periods for which we have data. Then we are proposing to calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the capital-related portion of the proposed 2022-based LTCH market basket and the 2017-based LTCH market basket are presented in Table EEEE 6.

TABLE VIII.D-06--PROPOSED 2022-BASED LTCH MARKET BASKET AND 2017-BASED LTCH MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2022-based 16 years	2017-based 18 years	2022-based 9 years	2017-based 9 years	2022-based 16 years	2017-based 18 years
1	0.051	0.046	0.094	0.093	0.037	0.031
2	0.053	0.047	0.099	0.096	0.039	0.032
3	0.055	0.046	0.103	0.101	0.042	0.033
4	0.057	0.048	0.107	0.109	0.046	0.036
5	0.059	0.048	0.112	0.113	0.049	0.038
6	0.059	0.051	0.116	0.117	0.052	0.042
7	0.060	0.052	0.119	0.119	0.055	0.045
8	0.062	0.053	0.123	0.124	0.059	0.048
9	0.064	0.055	0.128	0.129	0.063	0.052
10	0.065	0.057	--	--	0.067	0.056
11	0.066	0.058	--	--	0.071	0.059
12	0.068	0.059	--	--	0.076	0.063
13	0.069	0.061	--	--	0.080	0.068
14	0.069	0.062	--	--	0.083	0.072
15	0.070	0.063	--	--	0.088	0.075
16	0.071	0.063	--	--	0.093	0.078
17		0.064	--	--		0.083
18		0.065	--	--		0.088
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VIII.D–06 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

c. Summary of Price Proxies of the Proposed 2022-Based LTCH Market Basket

Table VIII.D–07 shows both the operating and capital price proxies for the proposed 2022-based LTCH market basket.

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TABLE VIII.D-07—PROPOSED PRICE PROXIES FOR THE PROPOSED 2022-BASED LTCH MARKET BASKET

Cost Description	Price Proxies
Total	
Compensation	
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals
Utilities	
Electricity and Other Non-Fuel Utilities	PPI for Commercial Electric Power
Fuel: Oil and Gas	Blend of PPIs
Professional Liability Insurance	
Malpractice	CMS Hospital Professional Liability Insurance Premium Index
All Other Products and Services	
All Other Products	
Pharmaceuticals	PPI Commodity for Pharmaceuticals for human use, prescription
Food: Direct Purchases	PPI for Processed Foods and Feeds
Food: Contract Services	CPI-U for Food Away From Home
Chemicals	Blend of PPIs
Medical Instruments	Blend of PPIs
Rubber and Plastics	PPI Commodity for Rubber and Plastic Products
Paper and Printing Products	Blend of PPIs
Miscellaneous Products	PPI Commodity for Finished Goods Less Food and Energy
All Other Services	
Labor-Related Services	
Professional Fees: Labor-Related	ECI for Total compensation for Private industry workers in Professional and related
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support
Installation, Maintenance, and Repair Services	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair
All Other: Labor-Related Services	ECI for Total compensation for Private industry workers in Service occupations
Nonlabor-Related Services	
Professional Fees: Nonlabor-Related	ECI for Total compensation for Private industry workers in Professional and related
Financial Services	ECI for Total compensation for Private industry workers in Financial activities
Telephone Services	CPI-U for Telephone Services
All Other: Nonlabor-Related Services	CPI-U for All Items Less Food and Energy
Capital-Related Costs	
Depreciation	
Building and Fixed Equipment	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (16 years)
Movable Equipment	PPI Commodity for machinery and equipment - vintage weighted (9 years)
Interest Costs	
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (16 years)
For Profit	Average yield on iBoxx AAA bonds - vintage weighted (16 years)
Other Capital-Related Costs	CPI-U for Rent of primary residence

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5. Proposed FY 2025 Market Basket Update for LTCHs

For FY 2025 (that is, October 1, 2024 through September 30, 2025), we propose to use an estimate of the proposed 2022-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update

for the LTCH PPS based on IHS Global, Inc.'s (IGI) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and total factor productivity (TFP).

Based on IGI's fourth quarter 2023 forecast with history through the third quarter of 2023, the projected market basket update for FY 2025 is 3.2 percent. This projected 2022-based LTCH market basket update reflects an increase in compensation prices (proxied by the ECIs for All Civilian workers in Hospitals) of 3.7 percent. IGI's forecast of the ECIs considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

We would note that the 10-year historical average (FY 2014 through FY 2023) growth rate of the proposed 2022-based LTCH market basket is 2.7 percent with a 10-year historical average growth rate of compensation prices equal to 2.9 percent over this same time period. Consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 3.2 percent for FY 2025. Furthermore, because the proposed FY 2025 annual update is based on the most recent market basket estimate for the 12-month period (currently 3.2 percent), we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2025 annual update in the final rule. (The proposed annual update to the LTCH PPS standard payment rate for FY 2025 is discussed in greater detail in section V.A.2. of the Addendum to this proposed rule.)

Using the current 2017-based LTCH market basket and IGI's fourth quarter 2023 forecast for the market basket components, the FY 2025 market basket update would be 3.1 percent (before taking into account any statutory adjustment). Therefore, the update based on the proposed 2022-based LTCH market basket is currently projected to be 0.1 percentage point higher for FY 2025 compared to the current 2017-based LTCH market basket. This higher update is primarily due to the higher Compensation cost weight in the proposed 2022-based market basket (61.8 percent) compared to the 2017-based LTCH market basket (53.2 percent). This is partially offset by the lower cost weight associated with All Other Services (such as Professional Fees and Installation, Maintenance, and Repair Services) for the proposed 2022-based LTCH market basket relative to the 2017-based LTCH market basket. Table VIII.D–08 compares the proposed 2022-based LTCH market basket and the 2017-based LTCH market basket percent changes.

TABLE VIII.D-08—PROPOSED 2022-BASED LTCH MARKET BASKET AND 2017-BASED LTCH MARKET BASKET PERCENT CHANGES, FYs 2020 THROUGH 2027

	Fiscal Year (FY)	Proposed 2022-Based LTCH Market Basket Index Percent Change	2017-Based LTCH Market Basket Index Percent Change
Historical Data	FY 2020	2.2	2.0
	FY 2021	2.6	2.8
	FY 2022	5.1	5.5
	FY 2023	5.1	4.8
	Average 2020-2023	**3.8**	**3.8**
Forecast	FY 2024	3.9	3.7
	FY 2025	3.2	3.1
	FY 2026	2.8	2.8
	FY 2027	2.8	2.8
	Average 2024-2027	**3.2**	**3.1**

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 4th quarter 2023 forecast

Over the historical time period covering FY 2020 through FY 2023, the average growth rate of the proposed 2022-based LTCH market basket is the same as the average growth rate of the 2017-based LTCH market basket. Over the forecasted time period covering FY 2024 through FY 2027, the average growth rate of the proposed 2022-based LTCH market basket is 0.1 percentage point higher than the average growth rate of the 2017-based LTCH market basket. This is driven by higher projected growth for FY 2024 and FY 2025 for the proposed 2022-based LTCH market basket, which is primarily a result of the higher proposed Compensation cost weight combined with faster projected growth in Compensation prices for FY 2024 and FY 2025 relative to projected prices for All Other Services. In FY 2026 and FY 2027 prices for these two aggregate cost categories are projected to grow at similar rates.

6. Proposed FY 2025 Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The labor-related share is determined by identifying the national average proportion of total costs that are related

to, influenced by, or vary with the local labor market. As discussed in more detail in this section of this rule and similar to the 2017-based LTCH market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58988), the labor-related share for FY 2024 was defined as the sum of the FY 2024 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related Services; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related Costs from the 2017-based LTCH market basket.

We propose to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2022-based LTCH market basket, we propose to include in the labor-related share for FY 2025 the sum of the FY 2025 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the Capital-Related cost weight from the proposed 2022-based LTCH market basket.

Similar to the 2017-based LTCH market basket, the proposed 2022-based LTCH market basket includes two cost categories for nonmedical Professional fees (including but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related. For the proposed 2022-based LTCH market basket, we propose to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-Related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2017-based LTCH market basket.

As was done for the 2017-based LTCH market basket, we propose to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588). A discussion of the composition of the survey and post-stratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

For the proposed 2022-based LTCH market basket, we propose to apply each of these percentages to the respective 2017 Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-Related costs. The Professional Fees: Labor-Related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-Related costs. This is the same methodology that we used to separate the 2017-based LTCH market basket professional fees category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories.

Effective for transmittal 18 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i*), the hospital Medicare Cost Report (CMS Form 2552–10, OMB No. 0938–0050) is collecting information on whether a hospital purchased professional services (for example, legal, accounting, tax preparation, bookkeeping, payroll, advertising, and/or management/consulting services) from an unrelated organization and if the majority of these expenses were purchased from unrelated organizations located outside of the main hospital's local area labor market. We encourage all providers to provide this information so we can potentially use these more recent data in future rulemaking to determine the labor-related share.

In the proposed 2022-based LTCH market basket, nonmedical professional fees that were subject to allocation based on these survey results represent approximately 3.6 percent of total costs (and are limited to those fees related to Accounting and Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we propose to apportion approximately 2.3 percentage points of the 3.6 percentage point figure into the Professional Fees: Labor-Related cost category and designate the remaining approximately 1.3 percentage points into the Professional Fees: Nonlabor-Related cost category.

In addition to the professional services as previously listed, for the 2022-based LTCH market basket, we propose to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as previously stated, into the labor-related and nonlabor-related cost categories. We propose to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office and, therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2017-based LTCH market basket, we propose for the 2022-based LTCH market basket to use the Medicare cost reports for LTCHs to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding their home office provider. Using information on the Medicare cost report, we compare the location of the LTCH with the location of the LTCH's home office. We propose to classify a LTCH with a home office located in their respective labor market if the LTCH and its home office are located in the same Metropolitan Statistical Area (MSA). Then we determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Home Office/Related Organization Contract Labor costs for those LTCHs that had home offices located in their respective MSA of total Home Office/Related Organization Contract Labor costs for LTCHs with a home office. We determined a LTCH's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology with the 2022 Medicare cost reports, we determined that 4 percent of LTCHs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective MSA, or local labor markets. Therefore, we are allocating 4 percent of the Home Office/Related Organization Contract Labor cost weight (0.1 percentage point = 3.7 percent × 4 percent) to the Professional Fees: Labor-Related cost weight and 96 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-Related cost weight (3.6 percentage

points = 3.7 percent × 96 percent). For comparison, for the 2017-based LTCH market basket we also allocated 4 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Labor-Related cost weight (85 FR 58924).

In summary, based on the two allocations mentioned earlier, we apportioned 2.4 percentage points (2.3 percentage points + 0.1 percentage point) of the Professional Fees and Home Office/Related Organization Contract Labor cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.6 percentage point of total costs) resulting in a total Professional Fees: Labor-Related cost weight of 3.0 percent.

As previously stated, we propose to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the Capital-Related cost weight from the proposed 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2025. Based on IGI's fourth quarter 2023 forecast of the proposed 2022-based LTCH market basket, the sum of the FY 2025 relative importance for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation Maintenance and Repair Services, and All Other: Labor-Related Services) is 68.9 percent. The portion of Capital costs that is estimated to be influenced by the local labor market is 46 percent, which is the same percentage applied to the 2017-based LTCH market basket. Since the relative importance for Capital is 8.4 percent of the proposed 2022-based LTCH market basket in FY 2025, we took 46 percent of 8.4 percent to determine the proposed labor-related share of Capital for FY 2025 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2025 of 72.8 percent (the sum of 68.9 percent for the operating cost and 3.9 percent for the labor-related share of Capital). Table VIII.D–09 shows the FY 2025 labor-related share using the proposed 2022-based LTCH market basket relative importance and the FY 2024 labor-related share using the 2017-based LTCH market basket.

TABLE VIII.D-09--PROPOSED FY 2025 LTCH LABOR-RELATED SHARE AND FY 2024 LTCH LABOR-RELATED SHARE

	FY 2025 Proposed Labor-Related Share based on Proposed 2022-based LTCH Market Basket[1]	FY 2024 Final Labor-Related Share based on 2017-based LTCH Market Basket[2]
Wages and Salaries	54.6	47.6
Employee Benefits	8.1	6.7
Professional Fees: Labor-Related[3]	3.0	4.4
Administrative and Facilities Support Services	0.5	1.0
Installation, Maintenance, and Repair Services	1.0	2.1
All Other: Labor-Related Services	1.7	2.5
Subtotal	**68.9**	**64.3**
Labor-Related portion of capital (46%)	3.9	4.2
Total Labor-Related Share	**72.8**	**68.5**

[1] IHS Global Inc. 4th quarter 2023 forecast.

[2]Based on IHS Global Inc. 2nd quarter 2023 forecast as published in the August 28, 2023 **Federal Register** (84 FR 59367).

[3]Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office/related organization contract labor costs.

The total difference between the FY 2025 labor-related share using the proposed 2022-based LTCH market basket (72.8 percent) and the FY 2024 labor-related share using the 2017-based LTCH market basket (68.5 percent) is 4.3 percentage points and this difference is primarily attributable to the revision to the base year cost weights for those categories included in the labor-related share. The 4.3 percentage points revision to the base year cost weights is a result of: (1) an 8.6 percentage points upward revision to the base year Compensation cost weight, which is derived using the LTCH Medicare cost report data; (2) a 3.6 percentage points downward revision in the base year labor-related categories associated with incorporating the 2017 Benchmark I–O data; and (3) a 0.7 percentage point downward revision in the base year labor-related portion of capital costs, which is derived using the LTCH Medicare cost report data.

IX. Proposed Quality Data Reporting Requirements for Specific Providers

A. Overview

In section IX. of the preamble of this proposed rule, we are seeking comment on and proposing changes to the following Medicare quality reporting programs:

- In section IX.B. of the preamble of this proposed rule, we have the following crosscutting quality program proposals or request for comment:

++ Proposed Adoption of the Patient Safety Structural Measure in the Hospital IQR Program and PCHQR Program.

++ Proposed Modification to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey in the Hospital IQR Program, Hospital VBP Program, and PCHQR Program.

++ Advancing Patient Safety and Outcomes Across the Hospital Quality Programs—Request for Comment.

- In section IX.C. of the preamble of this proposed rule, the Hospital IQR Program.
- In section IX.D. of the preamble of this proposed rule, the PCHQR Program.
- In section IX.E. of the preamble of this proposed rule, the LTCH QRP.
- In section IX.F. of the preamble of this proposed rule, the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

B. Crosscutting Quality Program Proposals and Request for Comment

1. Proposed Adoption of the Patient Safety Structural Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination for the Hospital Inpatient Quality Reporting (IQR) Program and the CY 2025 Reporting Period/FY 2027 Program Year for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

a. Background

A foundational commitment of providing healthcare services is to ensure safety, as embedded in the centuries-old Hippocratic Oath, ''First, do no harm.'' Yet, the landmark reports *To Err is Human* [182] and *Crossing the Quality Chasm* [183] surfaced major deficits in healthcare quality and safety. These reports resulted in widespread awareness of the alarming prevalence of patient harm and, over the past two decades, healthcare facilities implemented various interventions and strategies to improve patient safety, with some documented successes.[184] However, progress has been slow, and preventable harm to patients in the clinical setting resulting in significant morbidity and mortality remains common. A recent systematic analysis of literature concluded that preventable mortality among inpatients results in approximately 22,165 preventable deaths annually.[185] In another recent study, researchers identified adverse events in almost one-quarter of admissions and showed that more than one-fifth were deemed preventable and almost one-third were considered serious (that is, caused harm that required intervention or prolonged recovery).[186]

Despite established patient safety protocols and quality measures, the COVID–19 public health emergency (PHE) strained the healthcare system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care. Since the onset of the COVID–19 PHE, the U.S. has seen marked declines in patient safety metrics, as evidenced by considerable increases in healthcare-associated infections (HAIs).[187] [188] Studies found that central line-associated blood stream infections (CLABSIs) in hospitals were 60 percent higher than predicted in the absence of COVID–19, catheter-associated urinary tract infections (CAUTIs) were 43 percent higher, and methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia infections were 44 percent higher. Studies have shown that these results were likely due at least in part to disrupted routine infection control practices during the COVID–19 pandemic.[189] [190] Notably, recent reports demonstrate that some HAI rates have begun to decrease towards pre-pandemic levels as the U.S. saw a 9 percent overall decrease in CLABSI, a 12 percent overall decrease in CAUTI and a 16 percent overall decrease in hospital onset MRSA bacteremia between 2021 and 2022 in acute care hospital settings.[191]

As healthcare facilities struggled to address the challenges posed by the COVID–19 PHE, safety gaps and risks in healthcare delivery were illuminated,[192] revealing a lack of resiliency in the healthcare system.[193] [194] Beyond HAIs, other preventable types of patient harm that were brought to the forefront by the COVID–19 PHE include occurrences of pressure injuries [195] and patient falls [196] among hospitalized patients.

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[182] Institute of Medicine (U.S.) Committee on Quality of Health Care in America, Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds.). (2000). To Err is Human: Building a Safer Health System. National Academies Press (U.S.).

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In addition to safety issues illuminated during the COVID–19 PHE, two other key patient safety indicators that are worth noting for their prevalence are postoperative respiratory failure [197] [198] [199] and acute kidney injuries (AKI).[200] [201]

While the COVID–19 PHE may have disrupted routine infection control practices, these key patient safety indicators nevertheless show the importance of addressing gaps in safety in order to save lives, provide equitable medical care, and ensure that the U.S. healthcare system is resilient enough to withstand future challenges. Now is the time to recommit to better safety practices for both patients and healthcare workers, establish new protocols, and implement early interventions that will save many lives from preventable harms.

To accomplish these goals, the federal government is taking a multi-pronged approach to improve safety and reduce preventable harm to patients. The Agency for Healthcare Research and Quality (AHRQ), on behalf of HHS, has established the National Action Alliance to Advance Patient and Workforce Safety as a public-private collaboration to improve both patient and workforce safety.[202] As described by AHRQ, the National Action Alliance is a partnership between HHS and its Federal agencies and private stakeholders, including healthcare systems, clinicians, allied health professionals, patients, families, caregivers, professional societies, patient and workforce safety advocates, the digital healthcare sector, health services researchers, employers, and payors interested in recommitting the U.S. to advancing patient and workforce safety to move toward zero harm in healthcare.[203]

In September 2023, the President's Council of Advisors on Science and Technology (PCAST) published the ''Report to the President: A Transformational Effort on Patient Safety,'' with a call to action to renew ''our nation's commitment to improving patient safety.'' [204] The PCAST report put forth the following recommendations as a part of the call to action: (1) Establish and maintain Federal leadership for the improvement of patient safety as a national priority; (2) Ensure that patients receive evidence-based practices for preventing harm and addressing risks; (3) Partner with patients and reduce disparities in medical errors and adverse outcomes; and (4) Accelerate research and deployment of practices, technologies, and exemplar systems of safe care.[205]

As part of this national recommitment to safety in healthcare, we are promoting the use of safety measures throughout our quality programs to identify and measure quality gaps and processes, and to make that information transparent and available to the public. Effective measurement is paramount to monitoring harm events, identifying key gaps, and tracking progress toward safer, more reliable care. Within CMS' hospital quality measurement programs, there are a number of outcome and process measures in use that capture specific conditions or procedures such as the Severe Sepsis and Septic Shock: Management Bundle measure, Patient Safety and Adverse Events Composite measure, Severe Obstetric Complications electronic clinical quality measure (eCQM), and the Safe Use of Opioids—Concurrent Prescribing eCQM. While these metrics are important, they are not sufficient by themselves to measure and incentivize investment in a resilient safety culture or the infrastructure necessary for sustainable high performance within the broad and complex domain of patient safety. The systems-level approach to patient safety maintains that errors and accidents in medical care are a reflection of system-level failures, rather than failings on the part of individuals.[206] There is a strong alignment among patient safety experts to shift to a more holistic, proactive, systems-based approach to patient safety.[207] [208] [209] [210] [211] [212] While each of our existing measures address processes and outcomes that encourage providers to improve patient safety for specific conditions or related to specific treatments, these measures do not address the overall culture in which the care is provided. Including a systems-level measure would contribute to a culture that improves performance on these individual metrics as well as improves safety for all care provided within the hospital.

To drive action and improvements in safety and address this gap in systems-level measurement for safety within the Hospital IQR and PCHQR Programs, we are proposing the adoption of the Patient Safety Structural measure, a new attestation-based measure that assesses whether hospitals demonstrate a structure, culture, and leadership commitment that prioritize safety. The Patient Safety Structural measure includes five complementary domains, each containing a related set of statements that aim to capture the most salient, evidenced-based, structural and cultural elements of safety. This measure is intended to be a foundational measure and designed to assess hospital implementation of a

Benefit Analysis of Implementation of an Evidence-Based Fall Prevention Program. *JAMA Health Forum, 4*(1), e225125. *https://doi.org/10.1001/jamahealthforum.2022.5125.*

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[203] AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. *https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html.*

[204] President's Council of Advisors on Science and Technology. (2023). Report to the President: A Transformational Effort on Patient Safety. *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.*

[205] President's Council of Advisors on Science and Technology. (2023). Report to the President: A Transformational Effort on Patient Safety. *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.*

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[207] National Patient Safety Foundation. Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human. Boston, MA: National Patient Safety Foundation; 2015.

[208] Gandhi, T. K., Feeley, D., & Schummers, D. (2020b). Zero Harm in Health Care. NEJM Catalyst, 1(2). *https://doi.org/10.1056/cat.19.1137.*

[209] Pronovost, P. Transforming patient safety: A sector-wide systems approach. Published January 8, 2015.

[210] Frankel A, Haraden C, Federico F, Lenoci-Edwards J. A Framework for Safe, Reliable, and Effective Care. White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017. (Available on *https://www.ihi.org/resources/white-papers/framework-safe-reliable-and-effective-care*).

[211] American College of Healthcare Executives and IHI/NPSF Lucian Leape Institute. Leading a Culture of Safety: A Blueprint for Success. Boston, MA: American College of Healthcare Executives and Institute for Healthcare Improvement; 2017.

[212] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement; 2020. (Available at *www.ihi.org/SafetyActionPlan*).

systems-based approach to safety best practices, as demonstrated by: leaders who prioritize and champion safety; organizational policies, protocols, goals, and metrics reflecting safety as a core value; a diverse group of patients and families meaningfully engaged with healthcare providers as partners in safety; practices indicative of a culture of safety; accountability and transparency in addressing adverse events; and continuous learning and improvement. This Patient Safety Structural measure is informed by the PCAST recommendations, *Safer Together: The National Action Plan to Advance Patient Safety*,[213] developed by the National Steering Committee for Patient Safety convened by the Institute for Healthcare Improvement (IHI), as well as scientific evidence from existing patient safety literature, and detailed input from patient safety experts, advocates, and patients. Combining this leadership level structural measure with other high priority safety outcome measures would result in a robust and complementary patient safety measure set.

We note that other safety measure adoption proposals in this FY 2025 IPPS/LTCH PPS proposed rule complement the goals we have outlined for the Patient Safety Structural measure. Interested parties are encouraged to review our proposals to adopt measures for Hospital Harm—Falls with Injury (section IX.C.5.c of the preamble of this proposed rule), Hospital Harm—Postoperative Respiratory Failure (section IX.C.5.b of the preamble of this proposed rule), and the adoption of two healthcare-associated infection measures (section IX.C.5.d of the preamble of this proposed rule).

b. Measure Alignment to Strategy

In addition to the other Federal safety initiatives noted previously, this measure also aligns with the CMS National Quality Strategy. Specifically, the CMS National Quality Strategy identifies four priority areas and eight goals, each with an identified objective, success target, and initial action steps for advancing a ''high-quality, safe, equitable, and resilient health care system for all individuals.'' [214] The Patient Safety Structural measure addresses the priority area Safety and Resiliency, and aligns with the goals to enable a responsive and resilient healthcare system to improve quality and to achieve zero preventable harm. For example, attestation statements within the measure require hospitals to confirm if their strategic plan includes publicly sharing their commitment to patient safety as a core value and outlines specific safety goals and associated metrics, including the goal of ''zero preventable harm.''

This measure aligns with our efforts under the CMS National Quality Strategy's goal of advancing equity and whole-person care.[215] As stated in the measure attestation under Domain 2: Strategic Planning & Organizational Policy (see Table VIII.B.1–01 of this proposed rule), ''Patient safety and equity in care are inextricable, and therefore equity, with the goal of safety for all individuals, must be embedded in safety planning, goal-setting, policy and processes.'' This measure furthers a patient-centered approach by promoting conversations on equity among hospital staff, leadership, and patients and caregivers that take into account the diverse communities served by participants in CMS programs and the particular needs of each hospital's own community.

The measure also aligns with our Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[216] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, interested parties, and measure requirements.[217] The Patient Safety Structural measure supports these efforts and is aligned with the Meaningful Measures Area of ''Safety'' and the Meaningful Measures 2.0 goal to ''Ensure Safe and Resilient Health Care Systems.'' This measure also supports the Meaningful Measures 2.0 priority to ''promote a safety culture within a health care organization.'' This attestation measure focused on patient safety policies, processes, and activities aims to help hospitals better understand priorities for improving safety and serve as a prompt for action to invest in the infrastructure and safety culture necessary to reduce preventable harm to patients. When measure results are made public, patients and families would be able to make informed decisions on what facilities are best for them.

c. Pre-Rulemaking Process and Measure Endorsement

As required under section 1890A of the Act, the Consensus-Based Entity (CBE), currently Battelle, established the Partnership for Quality Measurement (PQM) to convene members comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List),[218] [219] by one of several committees convened by the PQM, for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the PCHQR and Hospital IQR Programs. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM *Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review,* including details of the measure review processes in Chapter 3.

[213] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement; 2020.

[214] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy Handout. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[215] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy Handout. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[216] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20.*

[217] Centers for Medicare & Medicaid Services. (2021). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.* We note that Meaningful Measures 2.0 is still under development.

[218] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[219] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

The CBE-established PQM also conducts the measure endorsement and maintenance (E&M) process to ensure a measure submitted for endorsement is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics—such as health status, language capabilities, race or ethnicity, and income level—and is consistent across types of health care providers, including hospitals and physicians (see section 1890(b)(2) of the Act). The PQM convenes several E&M project groups twice yearly, formally called the E&M Committees, each comprised of an E&M Advisory Group and an E&M Recommendations Group, to vote on whether a measure meets certain quality measure criteria. More details regarding the E&M process may be found in the PQM *Endorsement and Maintenance (E&M) Guidebook,* including details of the measure endorsement process in the section titled, ''Endorsement and Review Process.''

For the voting procedures of the PRMR and E&M processes, the PQM utilizes the Novel Hybrid Delphi and Nominal Group (NHDNG) multi-step process, which is an iterative consensus-building approach aimed at a minimum of 75 percent agreement among voting members, rather than a simple majority vote, and supports maximizing the time spent to build consensus by focusing discussion on measures where there is disagreement. For example, the PRMR Hospital Recommendation Group can reach consensus and have the following voting results: (A) Recommend, (B) Recommend with conditions (with 75 percent of the votes casted as recommend with conditions or 75 percent between recommend and recommend with conditions), and (C) Do not recommend. If no voting category reaches 75 percent or greater (including the combined [A] recommend and [B] recommend with conditions), the PRMR Hospital Recommendation Group did not come to consensus and the voting result is 'Consensus not reached.' Consensus not reached signals continued disagreement amongst the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. More details regarding the PRMR voting procedures may be found in Chapter 4 of the PQM *Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.* More details regarding the E&M voting procedures may be found in the PQM *Endorsement and Maintenance (E&M) Guidebook.*

(1) Recommendation From the Pre-Rulemaking and Measure Review Process

As part of the PRMR process, the PRMR Hospital Recommendation Group reviewed the Patient Safety Structural measure (MUC2023–188) during a meeting on January 18 and 19, 2024. The Patient Safety Structural measure was included for consideration in the Hospital IQR and PCHQR Programs on the publicly available ''2023 Measures Under Consideration List'' (MUC List).[220]

The voting results of the PRMR Hospital Recommendation Group for the Patient Safety Structural measure for the Hospital IQR Program were: eight members of the group recommended adopting the measure into the Hospital IQR Program without conditions; five members recommended adoption with conditions; three committee members voted not to recommend the measure for adoption. Additionally, nine members of the group recommended adopting the measure into the PCHQR Program without conditions; four members recommended adoption with conditions; three committee members voted not to recommend the measure for adoption. Taken together, 81.3 percent of the votes were recommended with conditions for each program. Thus, the committee reached consensus and recommended the Patient Safety Structural measure for the Hospital IQR Program and the PCHQR Program with conditions.

As mentioned previously, five members of the voting committee recommended the adoption of this measure into the Hospital IQR Program with conditions and four members of the voting committee recommended the adoption of this measure into the PCHQR Program with conditions. Those conditions were: the publication of an implementation guide that clearly documents how safety is to be measured; and using data to narrow the scope before approving the measure for programs. An attestation guide will be available at the time of the publication of this proposal. Data obtained from the measure's national use would allow us to evaluate the effectiveness of, and the potential to narrow the future scope of, the proposed attestations. Therefore, we are proposing this measure for adoption because we have adequately addressed the conditions raised by the PRMR Hospital Recommendations Group.

In addition to the formal voting results on the adoption of the Patient Safety Structural measure, we note that the majority of public comments received on this measure during the PRMR process were supportive, with 91 out of 97 public comments (94%) either supporting (81) adoption or supporting adoption with conditions (10). Comments in support of this proposal included the need for a zero preventable harm goal, robust hospital leadership, developing trust through transparency, and the involvement of patients and their families in safety work. We thank the large number of patients, family members, and other interested parties who publicly participated in the PRMR process.

(2) Endorsement and Measure Review

We are proposing to adopt this measure into the Hospital IQR Program and the PCHQR Program despite the measure not being endorsed by the CBE. Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that each measure specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, and section 1866(k)(3)(A) of the Act imposes the same requirement for measures specified for use in the PCHQR Program. Sections 1886(b)(3)(B)(viii)(IX)(bb) and 1866(k)(3)(B) of the Act state, however, that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We reviewed measures endorsed by both the CBE which currently holds the contract under section 1890(a) of the Act and measures endorsed by the entity which formerly held that contract and were unable to identify any other CBE-endorsed measures on strategies and practices to strengthen hospitals' systems and culture for safety. In light of the lack of endorsed measures on this specified area or medical topic, we have determined that it would be appropriate to use a measure that is not endorsed by the CBE. This measure is relevant to enhanced health outcomes. As described in the background section for this measure (section IX.B.1.a. of this proposed rule), medical errors and

[220] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

adverse events occur frequently and lead to adverse patient outcomes. This measure is designed to identify hospitals that practice a system-based approach to safety and embrace the importance of a safety culture. Demonstrating a structure, culture, and leadership commitment that prioritizes safety can improve care and outcomes for all patients.[221] The validity, feasibility and relevance of the measure have been thoroughly vetted by a Technical Expert Panel (TEP) convened by a CMS contractor and comprised of thought leaders in the field.[222] In response to the question of whether the domains capture the most important elements for advancing patient safety, most TEP members agreed that they do.[223] Furthermore, the measure developers engaged the members of the TEP for their operational and clinical expertise to assure that each domain was actionable and measurable.[224] As noted, the PRMR Hospital Committee received a total of 91 public comments expressing support for the Patient Safety Structural measure.[225] Most commenters were patients and family members who described their individual experiences with the medical system and preventable harms to which they were exposed. These commenters then emphasized the importance of the Patient Safety Structural measure's intent and domains for improving patient safety related to these experiences.[226] Due to the rigorous alignment with patient safety guidelines and literature as noted within the Background section of this proposal, as well as strong support from expert stakeholders, patients, and caregivers as noted above, we are confident that the foundational principles are sound, and the specifications are attainable, measurable, and actionable. We intend to submit the measure for future CBE endorsement.

[221] DiCuccio MH. The Relationship Between Patient Safety Culture and Patient Outcomes: A Systematic Review. J Patient Saf. 2015;11(3):135–42. doi:10.1097/PTS.0000000000000058.

[222] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. Summary of Technical Expert Panel (TEP) Meetings Patient Safety Structural Measure (PSSM). Available at: *https://mmshub.cms.gov/sites/default/files/PSSM-TEP-Summary-Report-202306.pdf.*

[223] ibid.

[224] ibid.

[225] Battelle—Partnership for Quality Measurement. Compiled MUC List Public Comment Posting. Available at: *https://p4qm.org/sites/default/files/2024-01/Compiled-MUC-List-Public-Comment-Posting.xlsx.*

[226] Battelle—Partnership for Quality Measurement. 2023 Measures Under Consideration Public Comment Summary Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-01/PRMR-Hospital-Public-Comments-Final-Summary.pdf.*

d. Measure Overview

The Patient Safety Structural measure is a structural measure developed to assess how well hospitals have implemented strategies and practices to strengthen their systems and culture for safety. The Patient Safety Structural measure comprises a set of complementary statements (or, attestations) that aim to capture the most salient, systems-oriented actions to advance safety. These statements should exemplify a culture of safety and leadership commitment to transparency, accountability, patient and family engagement, and continuous learning and improvement. Table IX.B.1–01 includes the five attestation domains and the corresponding attestation statements.

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TABLE IX.B.1-01: THE PATIENT SAFETY STRUCTURAL MEASURE'S FIVE DOMAIN ATTESTATIONS

Attestation Domains	**Attestation Statements: Attest yes or no to each statement. (Note: Affirmative attestation of all statements within a domain would be required for the hospital to receive a point for the domain)**
Domain 1: Leadership Commitment to Eliminating Preventable Harm	
The senior leadership and governing board at hospitals set the tone for commitment to patient safety. They must be accountable for patient safety outcomes and ensure that patient safety is the highest priority for the hospital. While the hospital leadership and the governing board may convene a board committee dedicated to patient safety, the most senior governing board must oversee all safety activities and hold the organizational leadership accountable for outcomes. Patient safety should be central to all strategic, financial, and operational decisions.	(A) Our hospital senior governing board prioritizes safety as a core value, holds hospital leadership accountable for patient safety, and includes patient safety metrics to inform annual leadership performance reviews and compensation. (B) Our hospital leaders, including C-suite executives, place patient safety as a core institutional value. One or more C-suite leaders oversee a system-wide assessment on safety (examples provided in the Attestation Guide),[227] and the execution of patient safety initiatives and operations, with specific improvement plans and metrics. These plans and metrics are widely shared across the hospital and governing board. (C) Our hospital governing board, in collaboration with leadership, ensures adequate resources to support patient safety (such as equipment, training, systems, personnel, and technology). (D) Reporting on patient and workforce safety events and initiatives (such as safety outcomes, improvement work, risk assessments, event cause analysis, infection outbreak, culture of safety, or other patient safety topics) accounts for at least 20% of the regular board agenda and discussion time for senior governing board meetings. (E) C-suite executives and individuals on the governing board are notified within 3 business days of any confirmed serious safety events resulting in significant morbidity, mortality, or other harm.
Domain 2: Strategic Planning & Organizational Policy	
Hospitals must leverage strategic planning and organizational policies to demonstrate a commitment to safety as a core value. The use of written policies and protocols that demonstrate patient safety is a priority and identify goals, metrics and practices to advance progress, is foundational to creating an accountable	(A) Our hospital has a strategic plan that publicly shares its commitment to patient safety as a core value and outlines specific safety goals and associated metrics, including the goal of "zero preventable harm." (B) Our hospital safety goals include the use of metrics to identify and address disparities in safety outcomes based on the patient characteristics determined by the hospital to be most important to health care outcomes for the specific populations served.

and transparent organization. Hospitals should acknowledge the ultimate goal of zero preventable harm, even while recognizing that this goal may not be currently attainable and requires a continual process of improvement and commitment. Patient safety and equity in care are inextricable, and therefore equity, with the goal of safety for all individuals, must be embedded in safety planning, goal-setting, policy, and processes.	(C) Our hospital has implemented written policies and protocols to cultivate a *just culture* that balances no-blame and appropriate accountability and reflects the distinction between human error, at-risk behavior, and reckless behavior.[228] (D) Our hospital requires implementation of a patient safety curriculum and competencies for all clinical and non-clinical hospital staff, including C-suite executives and individuals on the governing board, regular assessments of these competencies for all roles, and action plans for advancing safety skills and behaviors. (E) Our hospital has an action plan for workforce safety with improvement activities, metrics and trends that address issues such as slips/trips/falls prevention, safe patient handling, exposures, sharps injuries, violence prevention, fire/electrical safety, and psychological safety.
Domain 3: Culture of Safety & Learning Health Systems	
Hospitals must integrate a suite of evidence-based practices and protocols that are fundamental to cultivating a hospital culture that prioritizes safety and establishes a learning system both within and across hospitals. These practices focus on actively seeking and harnessing information to develop a proactive, hospital-wide approach to optimizing safety and eliminating preventable harm. Hospitals must establish an integrated infrastructure (that is, people and systems working collaboratively) and foster psychological safety among staff to effectively and reliably implement these practices.	(A) Our hospital conducts a hospital-wide culture of safety survey using a validated instrument annually, or every2 years with pulse surveys on target units during non-survey years. Results are shared with the governing board and hospital staff and used to inform unit-based interventions to reduce harm. (B) Our hospital has a dedicated team that conducts event analysis of serious safety events using an evidence-based approach, such as the National Patient Safety Foundation's Root Cause Analysis and Action (RCA2)[229]. (C) Our hospital has a patient safety metrics dashboard and uses external benchmarks (such as CMS Star Ratings or other national databases) to monitor performance and inform improvement activities on safety events (such as: medication errors, surgical/procedural harm, falls, pressure injuries, diagnostic errors, and healthcare-associated infections). (D) Our hospital implements a minimum of 4 of the following high reliability practices: • Tiered and escalating (for example, unit, department, facility, system) safety huddles at least 5 days a week, with 1 day being a weekend, that include key clinical and non-clinical (for example, lab, housekeeping, security) units and leaders, with a method in place for follow-up on issues identified. • Hospital leaders participate in monthly rounding for safety on all units, with C-suite executives rounding at least quarterly, with a method in place for follow-up on issues identified. • A data infrastructure to measure safety, based on patient safety evidence (for example, systematic reviews, national guidelines) and data from the electronic medical record that enables identification and tracking of serious safety events and precursor events. These data are shared with C-suite executives at least monthly, and the governing board at every regularly scheduled meeting.

	• Technologies, including a computerized physician order entry system and a barcode medication administration system, that promote safety and standardization of care using evidence-based practices. • The use of a defined improvement method (or hybrid of proven methods), such as Lean, Six Sigma, Plan-Do-Study-Act, and/or high reliability frameworks. • Team communication and collaboration training of all staff. • The use of human factors engineering principles in selection and design of devices, equipment, and processes. (E) Our hospital participates in large-scale learning network(s) for patient safety improvement (such as national or state safety improvement collaboratives), shares data on safety events and outcomes with these network(s),and has implemented at least one best practice from the network or collaborative.
Domain 4: Accountability & Transparency	
Accountability for outcomes, as well as transparency around safety events and performance, represent the cornerstones of a culture of safety. For hospital leaders, clinical and non-clinical staff, patients, and families to learn from safety events and prevent harm, there must exist a culture that promotes event reporting without fear or hesitation, and safety data collection and analysis with the free flow of information.	(A) Our hospital has a confidential safety reporting system that allows staff to report patient safety events, near misses, precursor events, unsafe conditions, and other concerns, and prompts a feedback loop to those who report. (B) Our hospital reports serious safety events, near misses and precursor events to a Patient Safety Organization (PSO) listed by the Agency for Healthcare Research and Quality (AHRQ)[230] that participates in voluntary reporting to AHRQ's Network of Patient Safety Databases. (C) Patient safety metrics are tracked and reported to all clinical and non-clinical staff and made public in hospital units (for example, displayed on units so that staff, patients, families, and visitors can see). (D) Our hospital has a defined, evidence-based communication and resolution program reliably implemented after harm events, such as AHRQ's Communication and Optimal Resolution (CANDOR) toolkit[231], that contains the following elements: • Harm event identification • Open and ongoing communication with patients and families about the harm event • Event investigation, prevention, and learning • Care-for-the-caregiver • Financial and non-financial reconciliation • Patient-family engagement and on-going support (E) Our hospital uses standard measures to track the performance of our communication and resolution program and reports these measures to the governing board at least quarterly.
Domain 5: Patient & Family Engagement	
The effective and equitable engagement of patients, families, and caregivers is essential to safer, better care. Hospitals must embed patients, families, and	(A) Our hospital has a Patient and Family Advisory Council that ensures patient, family, caregiver, and community input to safety-related activities, including representation at board meetings,

caregivers as co-producers of safety and health through meaningful involvement in safety activities, quality improvement, and oversight.	consultation on safety goal-setting and metrics, and participation in safety improvement initiatives. (B) Our hospital's Patient and Family Advisory Council includes patients and caregivers of patients who are diverse and representative of the patient population. (C) Patients have comprehensive access to and are encouraged to view their own medical records and clinician notes via patient portals and other options, and the hospital provides support to help patients interpret information that is culturally and linguistically appropriate as well as submit comments for potential correction to their record. (D) Our hospital incorporates patient and caregiver input about patient safety events or issues (such as patient submission of safety events, safety signals from patient complaints or other patient safety experience data, patient reports of discrimination). (E) Our hospital supports the presence of family and other designated persons (as defined by the patient) as essential members of a safe care team and encourages engagement in activities such as bedside rounding and shift reporting, discharge planning, and visitation 24 hours a day, as feasible.

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e. Measure Calculation

The Patient Safety Structural measure consists of five domains, each representing a complementary but separate safety commitment. Each of the five domains include five related attestation statements. Hospitals would need to evaluate and determine whether they can affirmatively attest to each domain. For a hospital to affirmatively attest to a domain, and receive a point for that domain, a hospital would evaluate and determine whether it engaged in each of the statements that comprise the domain (see Table IX.B.1–01), for a total of five possible points (one point per domain). A hospital would not be able to receive partial points for a domain.

For example, for Domain 2 (''Strategic Planning & Organizational Policy''), a hospital would evaluate and determine whether it meets the statements related to its strategic plan (Statement A), its safety goals (Statement B), policies and protocols for a *just culture* (Statement C), a patient safety curriculum and competencies for all hospital staff (Statement D), and an action plan for workforce safety (Statement E) (see Table IX.B.1–01). If its plan meets all five of these statements, the hospital would attest ''yes'' to each of the 5 attestation statements and would receive one point for Domain 2. If, for example, its plan only meets Statement A and Statement B, but does not meet Statement C, Statement D, and Statement E, the hospital would attest ''yes'' to Statement A and Statement B, attest ''no'' to Statement C, Statement D, and Statement E, and receive zero points for Domain 2. The hospital's overall score for the Patient Safety Structural measure can range from a total of zero to five points. If a hospital is comprised of more than one acute care hospital facility under one CCN, all such facilities reporting under the same CCN would need to satisfy these criteria in order for the hospital to affirmatively attest and receive points.

For more details on the measure specifications and the attestation guide for the Hospital IQR Program, we refer readers to the Proposed Measures tab under the IQR Measures page on QualityNet at: *https://qualitynet.com.gov/inpatient/iqr/proposedmeasures.* For more details on the measure specifications for the PCHQR Program, we refer readers to the CMS Measures Inventory Tool (CMIT) with the file name ''Patient Safety Structural Measure'' at: *https://cmit.cms.gov/cmit/#/.*

f. Data Submission and Reporting

We are proposing that hospitals would be required to submit information for the Patient Safety Structural measure once annually using the data submission and reporting standard procedures set forth by the CDC for the National Healthcare Safety Network (NHSN). Presently, hospitals report measure data to the CDC NHSN on a monthly or quarterly basis, depending on the measure. Under the data submission and reporting process for the Patient Safety Structural measure, hospitals would be required to submit data once annually. We refer readers to the CDC's NHSN website (*https://www.cdc.gov/nhsn/index.html*) for data submission and reporting procedures; information more specific to the Patient Safety Structural measure will be available through NHSN should this proposal be finalized. We refer readers to sections IX.C.9. and IX.D.4 of the preamble of this proposed rule for more details on our previously finalized data submission and deadline requirements for structural measures in the Hospital IQR Program and PCHQR Program, respectively. We further refer readers to sections IX.C.9. and IX.D.4 of the preamble of this proposed rule for more details on our previously finalized data submission requirements for measures submitted via the CDC NHSN in the Hospital IQR Program and

[227] Centers for Medicare & Medicaid Services, Patient Safety Structural Measure Attestation Guide, version 1.0, available at both: *https://qualitynet.com.gov/inpatient/iqr/proposedmeasures* and *https://qualitynet.com.gov/pch/pchqr/proposedmeasures.* We note that examples provided in this guide are for illustrative purposes.

[228] A just culture is defined by the Agency for Healthcare Research and Quality as a system that holds itself accountable, holds staff members accountable, and has staff members that hold themselves accountable. (The CUSP Method. *https://www.ahrq.gov/hai/cusp/index.html.)*

[229] Agency for Healthcare Research and Quality. (2019, September 7). Root Cause Analysis. *https://psnet.ahrq.gov/primer/root-cause-analysis.*

[230] Agency for Healthcare Research and Quality. Federally-Listed Patient Safety Organizations (PSOs). Retrieved January 5, 2024, from *https://pso.ahrq.gov/pso/listed?f%5B0%5D=resources_provided%3A2.*

[231] Agency for Healthcare Research and Quality. (2022). Communication and Optimal Resolution (CANDOR). *https://www.ahrq.gov/patient-safety/settings/hospital/candor/index.html.*

PCHQR Program, respectively. We propose to adopt the Patient Safety Structural measure in the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination and the PCHQR Program beginning with the CY 2025 reporting period/FY 2027 program year. Hospitals participating in the Hospital IQR Program and the PCHQR Program would satisfy their reporting requirement for the measure as long as they attest ''yes'' or ''no'' to each attestation statement in all five domains.

We are proposing to publicly report the hospital's measure performance score, which would range from 0 to 5 points, on an annual basis on Care Compare beginning in fall 2026 and on the Provider Data Catalog available at *data.cms.gov* for the PCHQR Program beginning in fall 2026.

We invite public comment on this proposal.

2. Proposal To Modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination for the Hospital IQR Program, the CY 2025 Reporting Period/FY 2027 Program Year for the PCHQR Program, and the FY 2030 Program Year for the Hospital VBP Program

a. Background

We refer readers to the FY 2024 IPPS/LTCH PPS final rule for our most recent updates to HCAHPS survey administration requirements and additional background information for the Hospital VBP Program, the Hospital IQR Program, and the PCHQR Program (88 FR 59083 through 59089, 88 FR 59196 through 59201, and 88 FR 59229 through 59232, respectively). For more details including information about patient eligibility for the HCAHPS Survey, please refer to the current HCAHPS Quality Assurance Guidelines, which can be found on the official HCAHPS website at: *https://hcahpsonline.org/en/quality-assurance/.*

The HCAHPS Survey measure (CBE #0166) asks recently discharged patients questions about aspects of their hospital inpatient experience that they are uniquely suited to respond to. The HCAHPS Survey as a whole is termed as a single ''measure'' for purposes of the Hospital IQR, PCHQR, and Hospital VBP Programs. We refer to the elements of the HCAHPS Survey that are publicly reported as ''sub-measures'' and to the questions within each sub-measure as survey ''questions,'' for the Hospital IQR and PCHQR Programs. Sub-measures are comprised of one, two, or three survey questions. For example, the sub-measure, ''Overall Hospital Rating,'' consists of one survey question and the sub-measure ''Communication with Nurses'' consists of three survey questions. In the Hospital VBP Program, the sub-measures of the HCAHPS Survey are referred to as ''dimensions.'' We refer readers to the HCAHPS On-Line website, *www.HCAHPSonline.org,* for a map of each question on the HCAHPS Survey and its sub-measures.

The current HCAHPS Survey measure consists of 29 survey questions that are organized into ten sub-measures in the Hospital IQR and PCHQR Programs, including 19 questions that ask ''how often'' or whether patients experienced a critical aspect of hospital care, rather than whether they were ''satisfied'' with their care. The current survey also includes three screener questions that direct patients to relevant questions, five questions to adjust for the mix of patients across hospitals, and two questions (race and ethnicity) that support Congressionally mandated reports outlined in the Healthcare Research and Quality Act of 1999.[232] [233] These components of the survey are used to construct the ten publicly reported HCAHPS Survey sub-measures in the Hospital IQR and PCHQR Programs. The survey questions are organized into eight dimensions in the Person and Community Engagement Domain for the Hospital VBP Program. We note that the Hospital VBP Program uses 8 dimensions while the Hospital IQR and PCHQR Programs use 10 sub-measures because ''Cleanliness'' and ''Quietness'' have been combined as a single dimension in the Hospital VBP Program for scoring purposes and the ''Recommend Hospital'' sub-measure is not included in the Hospital VBP Program. The rationale for combining these elements of the survey is described further in section IX.B.2.g(3) of the preamble of this proposed rule and can be found in the Hospital Inpatient VBP Program final rule (76 FR 26497 through 26526). The current HCAHPS Survey can be found at *https://hcahpsonline.org/en/survey-instruments/.*

[232] Library of Congress. Healthcare Research and Quality Act of 1999, Public Law 106–129, 113 Stat. 1653. Available at: *https://www.congress.gov/106/plaws/publ129/PLAW-106publ129.pdf.*

[233] Agency for Healthcare Research and Quality. (2023) 2023 National Healthcare Quality and Disparities Report. Available at: *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr23/index.html.*

b. Overview of Proposal To Modify the HCAHPS Survey Measure

The proposed updated HCAHPS Survey would result in a survey with 32 questions that make up a total of 11 sub-measures, with seven of those sub-measures being multi-question sub-measures and the other four sub-measures being single-question sub-measures. Four of the multi-question sub-measures and three of the single-question sub-measures in the updated version of the HCAHPS Survey would remain unchanged from those that are in the current version of the HCAHPS Survey. We outline the specific updates below. We are proposing to adopt the updated HCAHPS Survey for the Hospital IQR and PCHQR Programs in section IX.B.2.e of the preamble of this proposed rule. The updates would result in the ability to use nine dimensions for the Hospital VBP Program, and we are proposing to adopt those updates in the Hospital VBP Program in section IX.B.2.g of the preamble of this proposed rule.

We identified the need for the updates to the HCAHPS Survey through focus groups and cognitive interviews with patients and caregivers, discussions with technical experts, and literature reviews that were conducted by a CMS contractor who made recommendations to CMS. A literature scan was used to compile and review items from existing surveys, focusing on topics not covered in the current HCAHPS Survey. CMS, patient, and provider stakeholders reviewed the questions identified through the scan. Four patient focus groups were conducted to assign importance to and inform the further development of potential new questions, while also refining existing questions. This replicates the approach taken during the original development of the HCAHPS Survey. The focus groups included people with both planned and unplanned hospital stays, a variety of racial and ethnic groups, and both older and younger adults. The focus groups used both an exploratory and confirmatory approach to explore new topics and confirm the topics we had identified through the survey literature. The group discussion explored what it means to have a quality patient experience and what participants thought of their hospital stay—what went well and what went poorly. Group discussions were conducted in English and Spanish.

The findings from the focus group informed the development of the updates to the HCAHPS Survey questions, including the newly developed questions that were tested in

cognitive interviews. Cognitive interviews were also conducted in English and in Spanish. Lastly, a CMS contractor also conducted a technical expert panel that provided feedback on the current survey content and the new content areas.

We have determined that adopting the proposed updated version of the HCAHPS Survey measure would amount to a minimal change in burden because the combination of removals and additions of survey questions would result in only an additional 45 seconds to complete the survey. The time required to complete the 32-question survey is estimated to average eight minutes. Additionally, prior to the removal of the ''Communication About Pain'' questions in the CY 2019 OPPS/ASC final rule (83 FR 59140 through 59149), the HCAHPS Survey previously included 32 questions. We refer readers to sections XII.B.4, XII.B.6, and XII.B.7 of the preamble of this proposed rule for more information on our estimated changes to the information collection burden.

The proposed adoption of the updated version of the HCAHPS Survey measure would not result in any changes to the survey administration, the data submission and reporting requirements, or the data collection protocols. The proposed updated version of the HCAHPS Survey measure includes three new sub-measures: the multi-item ''Care Coordination'' sub-measure, the multi-item ''Restfulness of Hospital Environment'' sub-measure, and the ''Information About Symptoms'' single-item sub-measure. The updated HCAHPS Survey measure also removes the existing ''Care Transition'' sub-measure and modifies the existing ''Responsiveness of Hospital Staff'' sub-measure. The seven new questions are as follows:

- During this hospital stay, how often were doctors, nurses and other hospital staff informed and up-to-date about your care?
- During this hospital stay, how often did doctors, nurses and other hospital staff work well together to care for you?
- Did doctors, nurses or other hospital staff work with you and your family or caregiver in making plans for your care after you left the hospital?
- During this hospital stay, how often were you able to get the rest you needed?
- During this hospital stay, did doctors, nurses and other hospital staff help you to rest and recover?
- During this hospital stay, when you asked for help right away, how often did you get help as soon as you needed?
- During this hospital stay, did doctors, nurses or other hospital staff give your family or caregiver enough information about what symptoms or health problems to watch for after you left the hospital?

As discussed more fully below, these new questions address aspects of hospital care identified by patients and then tested in the 2021 HCAHPS Survey large-scale mode experiment described in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59196 through 59197) as important to measuring the quality of hospital care.

The proposed updated HCAHPS Survey measure would no longer include the following four questions:

- During this hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?
- During this hospital stay, staff took my preferences and those of my family or caregiver into account in deciding what my health care needs would be when I left.
- When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.
- When I left the hospital, I clearly understood the purpose for taking each of my medications.

In the updated HCAHPS Survey measure, the question on the use of the call button is removed in response to hospital input indicating that call buttons have been replaced by other mechanisms (such as a direct phone line). The other questions are removed because they do not follow standard Consumer Assessment of Healthcare Providers & Systems (CAHPS) question wording and were perceived as duplicative of existing and new survey questions by the patients who participated in our content testing.

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TABLE IX.B.2-01 CROSSWALK OF UPDATED HCAHPS SURVEY QUESTIONS TO UPDATED HCAHPS SURVEY SUB-MEASURES

Updated HCAHPS Survey Questions	Updated HCAHPS Survey Sub-Measure
During this hospital stay, how often did nurses treat you with courtesy and respect?	Communication with Nurses
During this hospital stay, how often did nurses listen carefully to you?	Communication with Nurses
During this hospital stay, how often did nurses explain things in a way you could understand?	Communication with Nurses
During this hospital stay, how often did doctors treat you with courtesy and respect?	Communication with Doctors
During this hospital stay, how often did doctors listen carefully to you?	Communication with Doctors
During this hospital stay, how often did doctors explain things in a way you could understand?	Communication with Doctors
During this hospital stay, how often were your room and bathroom kept clean?	Single Item Sub-Measure: Cleanliness
During this hospital stay, how often were you able to get the rest you needed?	Restfulness of Hospital Environment**◆
During this hospital stay, how often was the area around your room quiet at night?	Restfulness of Hospital Environment**◆
During this hospital stay, did doctors, nurses and other hospital staff help you to rest and recover?	Restfulness of Hospital Environment**◆
During this hospital stay, how often were doctors, nurses and other hospital staff informed and up-to-date about your care?	Care Coordination**
During this hospital stay, how often did doctors, nurses and other hospital staff work well together to care for you?	Care Coordination**
Did doctors, nurses or other hospital staff work with you and your family or caregiver in making plans for your care after you left the hospital?	Care Coordination**
How often did you get help in getting to the bathroom or in using a bedpan as soon as you wanted?	Responsiveness of Hospital Staff*
During this hospital stay, when you asked for help right away, how often did you get help as soon as you needed?	Responsiveness of Hospital Staff*
Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?	Communication About Medicines

Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?	Communication About Medicines
Did doctors, nurses or other hospital staff give your family or caregiver enough information about what symptoms or health problems to watch for after you left the hospital?	Single Item Sub-Measure: Information about Symptoms**
During this hospital stay, did doctors, nurses or other hospital staff talk with you about whether you would have the help you needed after you left the hospital?	Discharge Information
During this hospital stay, did you get information in writing about what symptoms or health problems to look out for after you left the hospital?	Discharge Information
Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?	Single Item Sub-Measure: Rating
Would you recommend this hospital to your friends and family?	Single Item Sub-Measure: Recommend

*As described in section IX.B.2.e(4) of this proposed rule, the updates include removing one question and adding a new question to the Responsiveness of Hospital Staff sub-measure.

** As described in section IX.B.2.b of this proposed rule, the updates include adding three new sub-measures: "Care Coordination," "Restfulness of the Hospital Environment," and "Information about Symptoms."

◆As described in section IX.B.2.e(2) of this proposed rule, the "Restfulness of Hospital Environment" sub-measure includes two new questions and one existing question (Quietness). We note that the "Quietness" question itself would remain unchanged in the updated HCAHPS Survey but would no longer be its own single-question sub-measure, and would instead be a question within the new "Restfulness of Hospital Environment" multi-question sub-measure.

We refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *https://www.hcahpsonline.org* for information regarding the HCAHPS Survey, its administration, oversight, and data adjustments. Detailed information on current HCAHPS Survey data collection protocols can be found in the HCAHPS Quality Assurance Guidelines, located at: *https://www.hcahpsonline.org/en/quality-assurance/*. The Quality Assurance Guidelines for the proposed updated HCAHPS Survey measure will be available in May 2024 at the official HCAHPS website.

c. Measure Alignment to Strategy

The HCAHPS Survey produces systematic, standardized, and comparable information about patients' experience of hospital care and promotes person-centered care. We have identified that patient experience measures, including the HCAHPS Survey, are foundational metrics, known as the Universal Foundation of quality measures. The Universal Foundation is intended to focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.[234] One of the goals of the National Quality Strategy [235] is to foster engagement and to bring the voices of patients to the forefront. As part of fostering engagement, we believe it is critical to hear the voices of individuals by obtaining feedback directly from patients on hospital performance and to incorporate their feedback as part of our comprehensive approach to quality.

d. Pre-Rulemaking Process and Measure Endorsement

(1) Recommendation From Pre-Rulemaking and Measure Review Process

We refer readers to section IX.B.1.c of the preamble of this proposed rule for details on the Pre-Rulemaking Measure Review (PRMR) process including the voting procedures the PRMR process uses to reach consensus on measure recommendations. The PRMR Hospital Committee, comprised of the PRMR Hospital Advisory Group and PRMR Hospital Recommendation Group, reviewed the proposed updated version of the HCAHPS Survey measure. The PRMR Hospital Recommendation Group reviewed the proposed updated HCAHPS Survey measure (MUC2023–146, 147, 148, 149) during a meeting on January 18–19, 2024, to vote on a recommendation with regard to use of

[234] Centers for Medicare & Medicaid Services (2023) Aligning Quality Measures Across CMS—the Universal Foundation. Available at: *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

[235] Centers for Medicare and Medicaid Services. (2024) CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

this measure for the PCHQR, Hospital IQR, and Hospital VBP Programs.

The PRMR Hospital Recommendation Group reached consensus for each of the three programs. For each program, they recommended the updates to the HCAHPS Survey measure with conditions.[236] The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the HCAHPS Survey within the Hospital IQR Program were: nine members of the group recommended adopting the updates without conditions; eight members recommended adoption with conditions; and two committee members voted not to recommend the updates for adoption. Taken together, 89.5 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended the updates to the HCAHPS Survey measure within the Hospital IQR Program with conditions.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the HCAHPS Survey within the Hospital VBP Program were: ten members of the group recommended adopting the updates without conditions; seven members recommended adoption with conditions; and two committee members voted not to recommend the updates for adoption. Taken together, 89.5 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended the updates to the HCAHPS Survey measure within the Hospital VBP Program with conditions.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the HCAHPS Survey within the PCHQR Program were: eleven members of the group recommended adopting the updates without conditions; six members recommended adoption with conditions; and two committee members voted not to recommend the updates for adoption. Taken together, 89.5 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended the updates to the HCAHPS Survey measure within the PCHQR Program with conditions.

The conditions that the committee recommended for all three programs were: CBE endorsement; consideration should be given to not extending the survey length and removal of overlapping items; use of adaptive questions in computerized administration to minimize items; and use of a mechanism to monitor trends in performance data over time.

We have taken these conditions into account and are proposing to adopt the updated HCAHPS Survey measure in all three programs in a manner that addresses the conditions raised by the committee. As noted in section IX.B.2.b of the preamble of this proposed rule and in response to the committee's condition that consideration be given to not extending the survey length, we note that the updated HCAHPS Survey measure would result in only an additional 45 seconds to complete the survey. We have estimated that the total time required to complete the 32-question survey is, on average, eight minutes. Additionally, in response to the committee's condition that consideration be given to removing overlapping items, we note that similar or overlapping questions were identified and considered for removal during the development and testing of the updated HCAHPS Survey measure, as described further in section IX.B.2.b of the preamble of this proposed rule. By developing items with patients' and caregivers' input and then empirically testing the new questions, we have ensured that the questions proposed in the updated HCAHPS Survey add unique, non-redundant information about key aspects of patient experience of care.[237] The committee also raised the condition that the survey use adaptive questions in computerized administration to minimize items. However, we note that adaptive questions in computerized administration would be infeasible in the mail mode of the HCAHPS Survey. Since all modes of survey administration that are available for the updated HCAHPS Survey (Mail Only, Phone Only, Mail-Phone, Web-Mail, Web-Phone, and Web-Mail-Phone) must be parallel, adaptive questions in computerized modes would not be appropriate for this measure at this time. We will take this feedback into consideration for any future potential changes to survey administration. In response to the committee's condition that a mechanism to monitor trends in performance data over time be used, we note that as part of administering each of these quality programs, we regularly monitor and evaluate hospitals' performance data trends. We would continually monitor these trends in performance with the updated HCAHPS Survey. We address the committee's condition of CBE endorsement in the following section.

(2) Measure Endorsement

We refer readers to section IX.B.1.c of the preamble of this proposed rule for details on the endorsement and maintenance (E&M) process including the measure evaluation procedures the CBE's E&M Committees use to evaluate measures and whether they meet endorsement criteria. The HCAHPS Survey was first endorsed in 2005 by the former CBE, the National Quality Forum. The former CBE renewed its endorsement of the current HCAHPS Survey in 2009, 2015, and 2019. The current HCAHPS Survey measure was most recently submitted to the CBE for maintenance endorsement review in the Spring 2019 cycle (CBE #0166) and was endorsed on October 25, 2019.[238] We note that the HCAHPS Survey measure remains an endorsed measure, and we intend to submit the updated HCAHPS Survey to the current CBE for endorsement in Fall 2025. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We have determined that the updates to the HCAHPS Survey measure are appropriately specified. The HCAHPS Survey measure remains endorsed, and the updated survey only modifies some of the questions and sub-measures within the survey. The HCAHPS Survey is designed to produce standardized information about patients' perspectives of care that allow objective and meaningful comparisons of hospitals on topics that are important to consumers, and these updates will improve the feedback we receive directly from patients on hospital performance. Therefore, we have determined it would be appropriate to propose to adopt these

[236] Battelle—Partnership for Quality Measurement. (2024). Pre-Rulemaking Measure Review Measures Under Consideration 2023 Recommendations Report. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final.pdf.*

[237] Battelle—Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.*

[238] Battelle—Partnership for Quality Measurement. HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey. Available at: *https://p4qm.org/measures/0166.*

updates to the measure before the updates receive CBE endorsement.

e. Proposal To Modify the HCAHPS Survey Measure for the Hospital IQR Program Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination and the PCHQR Program Beginning With the CY 2025 Reporting Period/FY 2027 Program Year

We are proposing to update the current HCAHPS Survey measure in the Hospital IQR and PCHQR Programs by adding three new sub-measures:

- ''Care Coordination'' sub-measure
- ''Restfulness of Hospital Environment'' sub-measure
- ''Information About Symptoms'' sub-measure

The updates also remove the existing ''Care Transition'' sub-measure and modify the existing ''Responsiveness of Hospital Staff'' sub-measure. The new ''Care Coordination'' sub-measure encompasses and broadens the current ''Care Transition'' sub-measure and the new questions in the ''Care Coordination'' sub-measure are more congruent with the other survey questions. The updated measure replaces one of the two survey questions in the current ''Responsiveness of Hospital Staff'' sub-measure with a new survey question that strengthens this sub-measure. The proposed updates to the HCAHPS Survey measure are detailed in section IX.B.2.b of the preamble of this proposed rule and we refer readers to the HCAHPS website at *https://www.hcahpsonline.org* for further details.

We propose that the updated HCAHPS Survey measure would be implemented in the Hospital IQR and PCHQR Programs beginning with patients discharged on January 1, 2025. Reporting of responses from the updated HCAHPS Survey measure for patients discharged between January 1, 2025 and December 31, 2025 would be used for the CY 2025 reporting period/FY 2027 payment determination for the Hospital IQR Program and for the CY 2025 reporting period/FY 2027 program year for the PCHQR Program. HCAHPS Survey sub-measures are publicly reported on a CMS website quarterly on a rolling basis, with the oldest quarter of data rolled off, and the most recent quarter rolled on with each refresh. As such, there would be a period during which some quarters of reporting data come from the current version of the HCAHPS Survey measure, and others come from the updated HCAHPS Survey measure. Through this time period, publicly reported HCAHPS Survey data for the Hospital IQR and PCHQR Programs would consist only of data from the eight unchanged sub-measures in the current HCAHPS Survey. When four quarters of the updated HCAHPS Survey data have been submitted, public reporting would reflect all of the modifications in the updated HCAHPS Survey measure. The proposed public reporting timeline of the updates to the HCAHPS Survey for the Hospital IQR and PCHQR Programs can be found in Table IX.B.2–02.

TABLE IX.B.2-02 PROPOSED TIMELINE FOR PUBLIC REPORTING OF THE HCAHPS SURVEY MEASURE IN THE HOSPITAL IQR AND PCHQR PROGRAMS

Table IX.B.2-02 Hospital IQR and PCHQR Programs Public Reporting Timeline for the Current and Proposed Updated Version of the HCAHPS Survey Measure		
Public Reporting Date	**Quarters of Data Publicly Reported♦**	**Publicly Reported Sub-Measures**
January 2025	Q2 2023 – Q1 2024	10 sub-measures in the current HCAHPS Survey
April 2025	Q3 2023 – Q2 2024	10 sub-measures in the current HCAHPS Survey
July 2025	Q4 2023 – Q3 2024	10 sub-measures in the current HCAHPS Survey
October 2025	Q1 2024 – Q4 2024	10 sub-measures in the current HCAHPS Survey
January 2026	Q2 2024 – Q1 2025	8 unchanged sub-measures in the current HCAHPS Survey*
April 2026	Q3 2024 – Q2 2025	8 unchanged sub-measures in the current HCAHPS Survey*
July 2026	Q4 2024 – Q3 2025	8 unchanged sub-measures in the current HCAHPS Survey*
October 2026	Q1 2025 – Q4 2025	11 sub-measures in the updated HCAHPS Survey**
January 2027	Q2 2025 – Q1 2026	11 sub-measures in the updated HCAHPS Survey
April 2027	Q3 2025 – Q2 2026	11 sub-measures in the updated HCAHPS Survey
July 2027	Q4 2025 – Q3 2026	11 sub-measures in the updated HCAHPS Survey
October 2027	Q1 2026 – Q4 2026	11 sub-measures in the updated HCAHPS Survey***

♦ We note that for the PCHQR Program, the HCAHPS Survey data are displayed on the Provider Data Catalog (PDC), while the HCAHPS Survey data for the Hospital IQR Program are displayed on Care Compare and in the PDC.

* Survey questions that comprise eight sub-measures on the current HCAHPS Survey would remain unchanged on the updated HCAHPS Survey. These sub-measures would continue to be publicly reported for the Hospital IQR and PCHQR Programs: "Communication with Nurses," "Communication with Doctors," "Communication about Medicines," "Discharge Information," "Overall Rating," "Recommend Hospital," "Cleanliness," and "Quietness."

** First public reporting date that there would be four quarters of data available for the proposed updated HCAHPS Survey data for public reporting under the Hospital IQR and PCHQR Programs.

*** The proposed updated HCAHPS Survey data will have been publicly reported for one full year.

(1) Addition of the Care Coordination Sub-Measure in the Proposed Updated HCAHPS Survey Measure

The ''Care Coordination'' sub-measure is a newly developed multi-question sub-measure and is composed of three new survey questions that ask patients how often hospital staff were informed and up-to-date about the patient's care, how often hospital staff worked well together to care for the patient, and whether hospital staff worked with the patient and family or caregiver in making plans for the patient's care post-hospitalization. The new questions address aspects of hospital care identified by patients participating in focus groups as important to measuring the quality of hospital care. Cognitive testing demonstrated the new questions were accurately and consistently interpreted. The ''Care Coordination'' sub-measure was shown to have good measurement properties (hospital-level reliability is 0.792 and Cronbach's alpha is 0.765) and construct validity in the 2021 mode experiment.[239] This sub-measure would fill a gap of furthering coordination efforts within the hospital setting and support our goals of including measures related to seamless care coordination and person-centered care. Across multiple focus groups, patients indicated that how well doctors, nurses, and other staff work together or as a team in caring for a patient was the most important information to have to understand what their care would be like in one hospital versus another.

(2) Addition of the Restfulness of Hospital Environment Sub-Measure in the Proposed Updated HCAHPS Survey Measure

The Restfulness of Hospital Environment—Hospital Patient sub-measure would fill a gap related to providing a restful and healing environment within the hospital setting and support our goal of including measures related to person-centered care. The ''Restfulness'' sub-measure is a newly developed multi-question sub-measure comprised of three survey questions: two new questions that ask how often patients were able to get the rest they needed, and whether hospital staff helped the patient to rest and recover, and one current survey question that asks how often the area around the patient's room was quiet at night (''Quietness''). Cognitive testing demonstrated the new questions were accurately and consistently interpreted. The 2021 mode experiment established that the ''Restfulness'' sub-measure has good measurement properties (hospital-level reliability is 0.870 and Cronbach's alpha is 0.735) and construct validity.[240] The existing ''Quietness'' sub-measure is currently a stand-alone question in the HCAHPS Survey. The updates to the HCAHPS Survey would move the stand-alone ''Quietness'' sub-measure into the new Restfulness of Hospital Environment sub-measure. In the proposed updated version of the HCAHPS Survey measure, the ''Quietness'' question itself would not change and would continue to be publicly reported.

(3) Addition of the Information About Symptoms Sub-Measure in the Proposed Updated HCAHPS Survey Measure

The ''Information About Symptoms'' sub-measure is a newly developed single-question sub-measure that would fill a gap of providing instructions and information for family and caregivers to take care of patients after discharge and supports our goal of including measures related to person-centered care. The new question captures an aspect of hospital care identified by patients participating in focus groups as important, and cognitive testing demonstrated the question was accurately and consistently interpreted. The sub-measure is a stand-alone question that asks the patient whether doctors, nurses, or other hospital staff gave the patient's family or caregiver enough information about symptoms or health problems to watch out for after the patient left the hospital. The sub-measure has good hospital level-reliability (0.729) at the expected average number of completed surveys per hospital.[241]

(4) Modification of the Responsiveness of Hospital Staff Sub-Measure in the Proposed Updated HCAHPS Survey Measure

The revisions to the ''Responsiveness of Hospital Staff'' sub-measure would entail adding one new survey question to this sub-measure and removing one current survey question from this sub-measure. The current survey question that would be removed from the ''Responsiveness of Hospital Staff'' sub-measure is the ''Call Button'' question. Input from hospitals indicated that call buttons have largely been replaced by other mechanisms (such as a direct phone line), and qualitative testing demonstrated that the new question captures all modes of requesting help. The 2021 mode experiment established that the modified ''Responsiveness of Hospital Staff'' sub-measure has good measurement properties (hospital-level reliability is 0.786 and Cronbach's alpha is 0.749) and construct validity.[242] Having patients report their experience of the responsiveness of hospital staff highlights an important aspect of hospital care from the patient's perspective about getting help for one's needs during a hospital stay, which is a component of person-centered care. These modifications to the ''Responsiveness of Hospital Staff'' sub-measure would fill a gap related to the care by nursing and other staff within the hospital setting and support our goals of including measures assessing person-centered care and the quality of hospital staff. The revised ''Responsiveness of Hospital Staff'' sub-measure would be comprised of two survey questions: one current survey question that asks how often patients received help in getting to the bathroom or in using a bedpan as soon as they wanted, and one new survey question that asks how often patients got help as soon as they needed it when they asked for help right away.

(5) Removal of the Care Transition Sub-Measure in the Proposed Updated HCAHPS Survey Measure

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513 through 53516), we added the three-question ''Care Transition'' sub-measure (CTM–3) to the HCAHPS Survey in the Hospital IQR Program. We finalized the addition of the HCAHPS Survey, including the CTM–3 sub-measure, for the PCHQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50844 through 50845). The updates to the HCAHPS Survey measure would remove this three-question sub-measure from the HCAHPS Survey measure and replace it with a new ''Care Coordination'' sub-measure, which would encompass and broaden the current ''Care Transition'' sub-

[239] Battelle—Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.*

[240] Battelle—Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.*

[241] Battelle—Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.*

[242] Battelle—Partnership for Quality Measurement. (2023). 2023 Pre-Rulemaking Measure Review (PRMR) Preliminary Assessment Report: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2023-12/PRMR-Hospital-Committee-PA-Final-Report.pdf.*

measure and is more congruent with the other questions in the HCAHPS Survey in terms of question form and response options. For these reasons, the updated version of the HCAHPS Survey measure removes the ''Care Transition'' sub-measure.

We invite public comment on the proposed adoption of the updated HCAHPS Survey measure for the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination and the PCHQR Program beginning with the CY 2025 reporting period/FY 2027 program year.

(6) Modification to the ''About You'' Section for the Hospital IQR, PCHQR, and Hospital VBP Programs

The ''About You'' questions are used either for patient-mix adjustment or for Congressionally-mandated reports.

The proposed changes to the ''About You'' section of the updated HCAHPS Survey would be:

- replacing the existing 'Emergency Room Admission' question with a new, 'Hospital Stay Planned in Advance' question;
- reducing the number of response options for the existing 'Language Spoken at Home' question;
- alphabetizing the response options for the existing ethnicity question; and
- alphabetizing the response options for the existing race question.

We note that to achieve the goal of fair comparisons across all hospitals that participate in HCAHPS Survey, it is necessary to adjust for factors that are not directly related to hospital performance but do affect how patients answer HCAHPS Survey questions. To ensure that differences in HCAHPS Survey results reflect differences in hospital quality only, HCAHPS Survey results are adjusted for patient-mix and mode of survey administration. Only the adjusted results are publicly reported and considered the official results. Information about the HCAHPS Survey patient-mix adjustment can be found at: *https://hcahpsonline.org/en/mode--patient-mix-adj.* We do not collect or adjust for patients' socioeconomic status, however, the HCAHPS Survey patient-mix adjustment does include patients' highest level of education, which can be related to socioeconomic status. Several questions on the HCAHPS Survey, as well as information drawn from hospital administrative data, are used for the patient-mix adjustment. The questions in the ''About You'' section of the survey that are used in patient-mix adjustment are:

- In general, how would you rate your overall health?
- In general, how would you rate your overall *mental or emotional health*?
- What is the highest grade or level of school that you have *completed*?
- What language do you *mainly* speak at home?

Administrative data provided by hospitals are also used in patient-mix adjustment, including patient's age, sex, and service line. Lag time, which is the number of days between a patient's discharge from the hospital and the return of the mail survey, or the final disposition of the telephone or interactive voice recognition (IVR) survey, is also used in patient-mix adjustment.[243]

Neither patient race nor ethnicity is used to adjust HCAHPS Survey results; these questions are included on the survey to support Congressionally-mandated reports. The adjustment model also addresses the effects of non-response bias. More information about the patient-mix adjustment coefficients for publicly reported HCAHPS Survey measure results can be found under ''Mode and Patient-Mix Adjustment'' at: *https://www.hcahpsonline.org.*

The current ''About You'' survey question that asks whether the patient was admitted to the hospital through the Emergency Room would be replaced with a new question that asks whether this hospital stay was planned in advance. ''Hospital stay planned in advance'' is being proposed for possible use as a patient-mix adjuster to distinguish between planned and unplanned stays. Cognitive testing indicated that ''Hospital stay planned in advance'' is better understood as intended than the current admission through the emergency room question. Unplanned stays are not within the hospital's control but can result in worse patient experiences than hospital stays that had been planned. Accounting for these differences in this preadmission characteristic allows for fairer comparisons of hospital performance.

To make survey administration more efficient and reduce respondent burden, especially in the telephone mode of survey administration, we are proposing that the response options for the 'Language Spoken at Home' question would be changed to: ''English,'' ''Spanish,'' ''Chinese,'' or ''Some other language.'' English, Spanish, and Chinese account for 98.2% of all HCAHPS Survey responses. The response options for the two race/ethnicity questions would be alphabetized to correspond to current best survey practices.

These proposed modifications would not be included in public reporting of the HCAHPS Survey and would not affect scoring under the Hospital VBP Program, but the 'Hospital Stay Planned in Advance' question would be employed in the patient-mix adjustment of survey responses.

We are proposing to implement these changes along with the proposed updated version of the HCAHPS Survey measure for the Hospital IQR, PCHQR, and Hospital VBP Programs described in the sections above.

f. Proposed Modifications to Scoring of the HCAHPS Survey for the Hospital VBP Program for the FY 2027 Through FY 2029 Program Years

(1) Background

As discussed above, we are proposing to adopt an updated version of the HCAHPS Survey measure so that IPPS hospitals and PCHs can report patient responses to the updated survey for purposes of the Hospital IQR Program and PCHQR Program, respectively, beginning with January 1, 2025 discharges. Although we are also proposing to adopt the updated version of the HCAHPS Survey measure for purposes of the Hospital VBP Program in section IX.B.2.g of the preamble of this proposed rule, section 1886(o)(2)(C)(i) precludes us from doing so until we have specified the updates under the Hospital IQR Program and included them on Care Compare for at least one year prior to the beginning of the performance period for such fiscal year. For this reason, we are proposing to adopt the updated version of the HCAHPS Survey measure beginning with the FY 2030 program year in the Hospital VBP Program. However, in order to relieve hospitals of the burden of having to use two different versions of the survey between FY 2027 and FY 2029, we are proposing that hospitals would be able to administer the updated version of the survey starting with January 1, 2025 discharges, and for the purposes of the Hospital VBP Program, we would only score hospitals on the six dimensions of the HCAHPS Survey that would remain unchanged from the current version of the survey.

(2) Proposed Scoring Modification of the HCAHPS Survey for the Hospital VBP Program for the FY 2027 Through FY 2029 Program Years

We are proposing to modify scoring to not include the ''Responsiveness of

[243] Elliott, M.N., Zaslavsky, A.M., Goldstein, E. et al. (2009) Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' Health Services Research. 44: 501–518. *https://doi.org/10.1111/j.1475-6773.2008.00914.x.*

Hospital Staff'' and ''Care Transition'' dimensions from scoring in the Hospital VBP Program's HCAHPS Survey measure in the Person and Community Engagement domain for the FY 2027 through FY 2029 program years. As noted above, we must collect and publicly report four quarters of data on the updated HCAHPS Survey measure before the updates could be adopted into the Hospital VBP Program. As described in section IX.B.2.g(2) of the preamble of this proposed rule, the updates to the ''Responsiveness of Hospital Staff'' dimension would be adopted in the Hospital VBP Program beginning with the FY 2030 program year along with the rest of the updates to the survey after the statutory requirements of section 1886(o)(2)(C)(i) of the Act have been met. As described in section IX.B.2.g(3), scoring on the updated ''Responsiveness of Hospital Staff'' dimension would begin with the FY 2030 program year. In addition, the ''Care Transition'' dimension in the current version of the survey would be removed permanently in the proposed updated HCAHPS Survey measure beginning with the FY 2030 program year. Until these updates can be adopted in the Hospital VBP Program beginning in FY 2030, we are proposing to exclude these dimensions from scoring for the FY 2027 through FY 2029 program years.

With the proposal to not score the ''Care Transition'' and ''Responsiveness of Hospital Staff'' dimensions in the Person and Community Engagement domain for the FY 2027 through FY 2029 program years, only six dimensions would continue to be used in the Hospital VBP Program for FY 2027, FY 2028, and FY 2029. By excluding these two dimensions from scoring within the Hospital VBP Program for the FY 2027 through FY 2029 program years, hospitals can continue to be scored on the remaining unchanged dimensions of the current HCAHPS Survey measure until the proposed updated HCAHPS Survey measure could be adopted for use in the Hospital VBP Program beginning in FY 2030.

We are proposing to score hospitals only on these six dimensions because we cannot score hospitals on any of the new or updated dimensions associated with the updated HCAHPS Survey measure until they have been adopted and reported in the Hospital IQR Program for one year prior to the beginning of the first performance period of their use in the Hospital VBP Program. These six unchanged dimensions of the HCAHPS Survey would be:

- ''Communication with Nurses,''
- ''Communication with Doctors,''
- ''Communication about Medicines,''
- ''Discharge Information,''
- ''Cleanliness and Quietness,'' and
- ''Overall Rating.''

We are proposing to modify the scoring such that for each of these six dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which would be summed across these six dimensions to create a pre-normalized HCAHPS Base Score of 0–60 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score would then be multiplied by 4/3 (1.3333333) and then rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the six unchanged dimensions would be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would be calculated using our current methodology and would continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score would only consider scores across the remaining six unchanged dimensions of the Person and Community Engagement domain. The final element of the scoring formula, which would remain unchanged from the current formula, would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50065) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49565), we adopted a similar modified scoring methodology when the Care Transition sub-measure was added to the current HCAHPS Survey in the Hospital VBP Program.

This proposed scoring modification would ensure that hospitals could continue to receive scores on the dimensions of the HCAHPS Survey that would remain unchanged in the current survey and would provide a period of transition until the Hospital VBP Program could adopt the updates to the survey. The updated version of the HCAHPS Survey measure would be adopted in the Hospital IQR and PCHQR Programs beginning with January 1, 2025 discharges, however, those updated sub-measures would not be scored as dimensions for the Hospital VBP Program until the FY 2030 program year. We reiterate that hospitals will only have to circulate one version of the HCAHPS Survey at a time.

We invite public comment on this proposal to modify scoring on the HCAHPS Survey measure in the Hospital VBP Program for the FY 2027 through FY 2029 program years to only score on the six dimensions discussed above.

g. Proposed Adoption of the Updated HCAHPS Survey Measure and Associated Scoring Modifications in the Hospital VBP Program Beginning With the FY 2030 Program Year

(1) Background

As described in section IX.B.2.e of the proposed rule, the modifications to the proposed updated version of the HCAHPS Survey measure include adding three new sub-measures, ''Care Coordination,'' ''Restfulness of Hospital Environment,'' and ''Information About Symptoms'' to the survey. As noted above, the updates also include removing the existing ''Care Transition'' sub-measure and modifying the existing ''Responsiveness of Hospital Staff'' sub-measure. In the Hospital VBP Program beginning with the FY 2030 program year, we are proposing to adopt the updated HCAHPS Survey measure, and we are therefore also proposing additional scoring modifications. This timeline would allow for the updated HCAHPS Survey measure to be adopted and publicly reported under the Hospital IQR Program for one year, as statutorily mandated. We describe the proposed adoption of these updates and scoring modifications in the following sections.

(2) Proposed Adoption of the Updated HCAHPS Survey Measure in the Hospital VBP Program Beginning With the FY 2030 Program Year

We are proposing to adopt the updated HCAHPS Survey measure in the Hospital VBP Program beginning with the FY 2030 program year to align with the adoption of the updated HCAHPS Survey measure that we are proposing to adopt in the Hospital IQR Program, as described in section IX.B.2.e of the preamble of this proposed rule. Under this proposal, the updated HCAHPS Survey measure will have been publicly reported for one year in the Hospital IQR Program prior to the beginning of the performance period for the HCAHPS Survey measure in the Hospital VBP Program for the FY 2030 program year, which consists of a performance period of CY 2028 and a baseline period of CY 2026.

We note that the number and content of dimensions from the proposed updated HCAHPS Survey in the Person and Community Engagement Domain in

the Hospital VBP Program in FY 2030 differs slightly from the number and content of the sub-measures in the Hospital IQR and PCHQR Programs. Namely, the ''Cleanliness'' and ''Information about Symptoms'' sub-measures are single-item sub-measures in the proposed updated HCAHPS Survey measure in the Hospital IQR and PCHQR Programs but they would be combined into one dimension in the proposed adoption of the updated HCAHPS Survey measure beginning with the FY 2030 Hospital VBP program year.

The proposed dimensions in the Person and Community Engagement Domain in the Hospital VBP Program beginning with the FY 2030 program year are:

- ''Communication with Nurses,''
- ''Communication with Doctors,''
- ''Responsiveness of Hospital Staff,''
- ''Communication about Medicines,''
- ''Cleanliness and Information About Symptoms,''
- ''Discharge Information,''
- ''Overall Rating of Hospital,''
- ''Care Coordination,'' and
- ''Restfulness of Hospital Environment.''

We refer readers to Table IX.B.2–03 for the timelines for the current and newly proposed HCAHPS Survey dimensions for the Hospital VBP Program.

In the proposed updated HCAHPS Survey measure, the ''Care Transition'' dimension is removed. The new ''Care Coordination'' dimension and the new ''Information about Symptoms'' question, which is included in the proposed new ''Cleanliness and Information about Symptoms'' dimension, encompass a broader depiction of person-centered care than does the ''Care Transition'' dimension. The proposed updated HCAHPS Survey measure includes the new ''Care Coordination'' dimension, the new ''Restfulness of the Hospital Environment'' dimension, and the new ''Cleanliness and Information about Symptoms'' dimension. We propose to begin using these three new dimensions in the Hospital VBP Program beginning with the FY 2030 program year. As noted in section IX.B.2.e(1) of the preamble of this proposed rule, the ''Care Coordination'' dimension would further coordination efforts within the hospital setting and support our goals of including measures related to seamless care coordination and person-centered care. Additionally, the new ''Restfulness of the Hospital Environment'' dimension is comprised of three survey questions: two new questions that ask how often patients were able to get the rest they needed, and whether hospital staff helped the patient to rest and recover, and one current survey question that asks how often the area around the patient's room was quiet at night (''Quietness'').

The proposed updated version of the HCAHPS Survey measure further modifies the current ''Cleanliness and Quietness'' dimension in two ways. In the FY 2030 program, the ''Quietness'' question would be removed from the ''Cleanliness and Quietness'' dimension and would instead be included in the new ''Restfulness of Hospital Environment'' dimension; however, the ''Quietness'' question itself would remain unchanged on the updated HCAHPS Survey. Additionally, in the FY 2030 program year, we propose to modify the ''Cleanliness and Quietness'' dimension to be called the ''Cleanliness and Information About Symptoms'' dimension, which would include the existing ''Cleanliness'' question and the new ''Information About Symptoms'' question from the updated HCAHPS Survey. The newly developed ''Information About Symptoms'' question asks the patient whether doctors, nurses, or other hospital staff gave the patient's family or caregiver enough information about symptoms or health problems to watch out for after the patient left the hospital.

We refer readers to section IX.B.2.b of the preamble of this proposed rule where we further describe the updates included in the updated HCAHPS Survey measure and to Table IX.B.2–03 for the timelines for the current and newly proposed HCAHPS Survey dimensions for the Hospital VBP Program.

TABLE IX.B.2-03 TIMELINES FOR CURRENT AND NEWLY PROPOSED HCAHPS SURVEY DIMENSIONS FOR THE HOSPITAL VBP PROGRAM

HCAHPS Survey Dimension	FY 2025 Program Year	FY 2026 Program Year	FY 2027 Program Year	FY 2028 Program Year	FY 2029 Program Year	FY 2030 Program Year
	Current HCAHPS Survey		Newly Proposed Transition Period			Newly Proposed Updated HCAHPS Survey
Communication with Nurses	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Reporting Period	CY 2026 Reporting Period
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	CY 2028 Performance Period
Communication with Doctors	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Baseline Period	CY 2026 Baseline Period
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	CY 2028 Performance Period
Responsiveness of Hospital Staff	CY 2019 Baseline Period*	CY 2022 Baseline Period	**	**	**	CY 2026 Baseline Period
	CY 2023 Performance Period	CY 2024 Performance Period	**	**	**	CY 2028 Performance Period
Communication about Medicines	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Baseline Period	CY 2026 Baseline Period
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	CY 2028 Performance Period
Cleanliness and Quietness of Hospital Environment	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Baseline Period	***
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	***
Discharge Information	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Baseline Period	CY 2026 Baseline Period
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	CY 2028 Performance Period
Overall Rating of Hospital	CY 2019 Baseline Period*	CY 2022 Baseline Period	CY 2023 Baseline Period	CY 2024 Baseline Period	CY 2025 Baseline Period	CY 2026 Baseline Period
	CY 2023 Performance Period	CY 2024 Performance Period	CY 2025 Performance Period	CY 2026 Performance Period	CY 2027 Performance Period	CY 2028 Performance Period
Care Transition	CY 2019 Baseline Period*	CY 2022 Baseline Period	#	#	#	#
	CY 2023 Performance Period	CY 2024 Performance Period	#	#	#	#
Care Coordination	♦	♦	♦	♦	♦	CY 2026 Baseline Period

	♦	♦	♦	♦	♦	CY 2028 Performance Period
Restfulness of Hospital Environment	♦	♦	♦	♦	♦	CY 2026 Baseline Period
	♦	♦	♦	♦	♦	CY 2028 Performance Period
Cleanliness and Information about Symptoms	♦	♦	♦	♦	♦	CY 2026 Baseline Period
	♦	♦	♦	♦	♦	CY 2028 Performance Period

*In the FY 2023 IPPS/LTCH PPS final rule, we finalized that these baseline periods would be January 1, 2019, through December 31, 2019 (87 FR 49111 through 49113).

** In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to not score the ''Responsiveness of Hospital Staff'' dimension for the FY 2027 through FY 2029 program years, and to score an updated version of this dimension beginning with the FY 2030 program year.

***In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to stop scoring on the ''Cleanliness and Quietness of Hospital Environment'' dimension beginning with the FY 2030 program year to align with the updates to the HCAHPS Survey that would move the ''Quietness'' question into the "Restfulness of Hospital Environment" dimension and would combine the ''Cleanliness'' question with the ''Information about Symptoms'' question to create the new, ''Cleanliness and Information about Symptoms'' dimension in the Hospital VBP Program.

In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to remove the ''Care Transition'' dimension from scoring in the Hospital VBP Program beginning with the FY 2027 program year.

♦In this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to begin scoring on three new dimensions, ''Care Coordination,'' ''Restfulness of Hospital Environment,'' and ''Cleanliness and Information about Symptoms'' in the Hospital VBP Program beginning with the FY 2030 program year.

We invite public comment on the proposal to adopt the updated HCAHPS Survey measure in the Hospital VBP Program beginning With the FY 2030 program year.

(3) Proposal To Modify Scoring of the HCAHPS Survey in the Hospital VBP Program Beginning With the FY 2030 Program Year

We are also proposing to adopt a new scoring methodology beginning with the FY 2030 program year. For each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) would be calculated, the larger of which would be summed across the nine dimensions to create a pre-normalized HCAHPS Base Score of 0–90 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score would then be multiplied by 8/9 (0.88888889) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions would be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points would then be calculated in the same manner as with the original HCAHPS Survey in the Hospital VBP Program and would continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score would consider scores across all nine of the Person and Community Engagement domain dimensions. The final element of the scoring formula, which would remain unchanged from the current formula in the Hospital VBP Program, would be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points, as before. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50065) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49565), we adopted a similar scoring methodology when the Care Transition dimension was added to the Person and Community Engagement domain in the Hospital VBP Program.

Additionally, we note that in the scoring of the current HCAHPS Survey measure in the Hospital VBP Program, the ''Cleanliness and Quietness'' dimension is the average of the publicly reported stand-alone ''Cleanliness'' and ''Quietness'' questions. As previously noted, the proposed adoption of the updated HCAHPS Survey measure would result in ''Quietness'' being removed from this dimension and included as a question in the new ''Restfulness of the Hospital Environment'' dimension, and ''Cleanliness'' would be combined with the new ''Information about Symptoms.'' Therefore, ''Quietness'' would be scored as part of the ''Restfulness of the Hospital Environment'' dimension in conjunction with the other questions under that dimension. For the proposed ''Cleanliness and Information about Symptoms'' dimension, we would take the average of the stand-alone ''Cleanliness'' and ''Information about Symptoms'' questions to obtain a score for the ''Cleanliness and Information about Symptoms'' dimension. For the purposes of the Hospital VBP Program, we are proposing these two questions be combined so as not to put more weight on these single-question dimensions compared to the rest of the HCAHPS Survey dimensions, which are multi-question dimensions (with the exception of Overall Rating). If these dimensions, ''Cleanliness'' and ''Information About Symptoms,'' were separated, ''Cleanliness,'' for example, as a single-question dimension, would receive as much weight as the ''Communication with Nurses'' dimension, which includes three questions. Therefore, the combined ''Cleanliness and Information about Symptoms'' dimension would be a two-question dimension that is more comparable to the other HCAHPS Survey dimensions in the Person and Community Engagement domain.

We invite public comment on this proposal to modify scoring of the HCAHPS Survey in the Hospital VBP Program beginning with the FY 2030 program year to account for the adoption of the updated HCAHPS Survey measure.

3. Advancing Patient Safety and Outcomes Across the Hospital Quality Programs—Request for Comment

The Hospital Readmissions Reduction Program was implemented to reduce

excess readmissions effective for discharges from applicable hospitals beginning on or after October 1, 2012. The program uses six claims-based measures to track unplanned inpatient admissions within 30 days following discharge. Using the data collected from these measures, we have observed that since the inception of the program, inpatient readmission rates for the conditions and procedures included in the program have gone down.[244]

However, studies have found a concurrent increase in patients who, after being discharged from an inpatient stay, visit the emergency department (ED) or receive observation services as an outpatient.[245] [246] [247] [248] [249] As a result, we are concerned that our hospital quality reporting and value-based purchasing programs may not be adequately incentivizing hospitals to improve quality of care by accounting for more types of post-discharge events, such as a return to the ED or the receipt of observation services.

From a patient perspective, unexpectedly returning to any acute care setting, including the ED, or receiving observation services after being discharged from an inpatient hospital stay,[250] is an undesirable outcome of care. Patients who are discharged from an inpatient stay but then make an unplanned return to the hospital may incur higher healthcare costs than those that do not return to the hospital setting due to potential out-of-pocket charges for the unplanned follow-up care. Research has found that the median out-of-pocket cost of observation services received by Medicare beneficiaries as outpatients was $448.94, with low-income beneficiaries being more likely to report being concerned about costs of follow-up care, as compared to higher income beneficiaries, and limiting health care utilization that could otherwise be deemed essential in response to higher out-of-pocket costs.[251]

While these unplanned returns to the hospital impose significant burden on patients, such visits can often be avoided with greater attention to care coordination.[252] This coordination can include addressing barriers such as poor health literacy or social determinants of health that complicate a patient's ability to follow post-discharge instructions, fill prescriptions, or alert hospital staff to new symptoms.[253] For example, in one study, nurses implemented evidence-based practices for transition care, including engaging in patient education, providing clear post-discharge instructions, and following up with patients via phone calls. The study found that 9.4 percent of patients who received such intervention were readmitted 30 days after discharge, compared to an 18.8 percent readmission rate among patients not receiving such interventions. Similarly, 19.8 percent of patients receiving evidence-based transitional care were readmitted within 90 days after discharge, compared to 31.5 percent among patients in the usual care group.[254] These findings indicate that supporting patients' discharges by proactively addressing potential barriers is effective in reducing unplanned readmissions.

Therefore, we are seeking ways to build on current measures in several quality reporting programs that account for unplanned patient hospital visits to encourage hospitals to improve discharge processes. Current measures include three Excess Days in Acute Care (EDAC) measures currently in the Hospital Inpatient Quality Reporting (IQR) Program, which estimate days spent in acute care within 30 days post discharge from an inpatient hospitalization for a principal diagnosis of the measure's specified condition. The acute care outcomes include ED visits, receipt of observation services, and unplanned readmissions.[255] The measures are:

- Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction (AMI), adopted in the FY 2016 IPPS/LTCH PPS final rule beginning with the FY 2018 payment determination (80 FR 49680 through 49682);
- Excess Days in Acute Care (EDAC) after Hospitalization for Heart Failure (HF), adopted in the FY 2016 IPPS/LTCH PPS final rule beginning with the FY 2018 payment determination (80 FR 49682 through 49690); and
- Excess Days in Acute Care (EDAC) after Hospitalization for Pneumonia, adopted in the FY 2017 IPPS/LTCH PPS final rule beginning with the FY 2019 payment determination (81 FR 57142 through 57148).

Another existing measure that CMS uses to assess unplanned hospital returns is the Hospital Visits After Hospital Outpatient Surgery measure. We adopted this measure into the Hospital Outpatient Quality Reporting (OQR) Program in the CY 2017 OPPS/ASC final rule beginning with the CY 2020 reporting period (81 FR 79764 through 79771) and the Rural Emergency Hospital Quality Reporting (REHQR) Program in the CY 2024 OPPS/ASC final rule beginning with the CY 2024 reporting period (88 FR 82064 through 82066). This measure's outcome includes any unplanned hospital visits (ED visits, receipt of observation services, or unplanned inpatient admissions) within seven days of outpatient surgery. The measure calculates facility-level measure scores based on the ratio of predicted to

[244] Medicare Hospital Quality Chartbook. National Rates over Time. Available at: *https://www.cmshospitalchartbook.com/visualization/national-rates-over-time.* Accessed March 12, 2024.

[245] Nuckols TK, Fingar KR, Barrett ML, et al. Returns to Emergency Department, Observation, or Inpatient Care Within 30 Days After Hospitalization in 4 States, 2009 and 2010 Versus 2013 and 2014. J Hosp Med. 2018;13(5):296–303.

[246] Shammas NW, Kelly R, Lemke J, et al. Assessment of Time to Hospital Encounter after an Initial Hospitalization for Heart Failure: Results from a Tertiary Medical Center. Cardiol Res Pract. 2018; 2018:6087367.

[247] Sabbatini AK, Joynt-Maddox KE, Liao JM, et al. Accounting for the growth of observation stays in the assessment of Medicare's hospital readmissions reduction program. JAMA Netw Open. 2022;5(11):e2242587.

[248] Sabbatini AK, Wright B. Excluding observation stays from readmission rates—what quality measures are missing. New Engl J Med. 2018;378(22):2062–2065.

[249] Wadhera RK, Joynt Maddox KE, Kazi DS, Shen C, Yeh RW. Hospital revisits within 30 days after discharge for medical conditions targeted by the Hospital Readmissions Reduction Program in the United States: national retrospective analysis. BMJ. 2019;366: l4563.

[250] Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. See additional explanation here: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c06.pdf.*

[251] Goldstein, J.N., Schwartz, J.S., McGraw, P. et al. ''Implications of cost-sharing for observation care among Medicare beneficiaries: a pilot survey''. BMC Health Serv Res 19, 149 (2019). *https://doi.org/10.1186/s12913-019-3982-8.*

[252] Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annu Rev Med. 2014;65:471–85. doi: 10.1146/annurev-med-022613–090415. Epub 2013 Oct 21.

[253] Hoyer EH, Brotman DJ, Apfel A, Leung C, Boonyasai RT, Richardson M, Lepley D, Deutschendorf A. Improving Outcomes After Hospitalization: A Prospective Observational Multicenter Evaluation of Care Coordination Strategies for Reducing 30-Day Readmissions to Maryland Hospitals. J Gen Intern Med. 2018 May; 33(5): 621–627. Published online 2017 Nov 27. doi: 10.1007/s11606–017–4218–4.

[254] Kripalani S, Chen G, Ciampa P, Theobald C, Cao A, McBride M, Dittus RS, Speroff T. A Transition Care Coordinator Model Reduces Hospital Readmissions and Costs. Contemp Clin Trials. 2019 Jun; 81: 55–61. Published online 2019 Apr 25. doi: 10.1016/j.cct.2019.04.014.

[255] Centers for Medicare & Medicaid Services. 2023 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

expected number of post-surgical hospital visits. By publicly reporting these scores, the measure encourages providers to engage in quality improvement activities to reduce unplanned follow-up visits (81 FR 79765).

While our hospital quality reporting and value-based purchasing programs currently encourage hospitals to address concerns about unplanned returns through several existing measures, we recognize that these measures, taken together, do not comprehensively capture unplanned patient returns to inpatient or outpatient care after discharge. The EDAC measures currently in the Hospital IQR Program only cover patients with a primary discharge of AMI, HF, or Pneumonia. Meanwhile, the Hospital Visits After Hospital Outpatient Surgery measure only covers patients discharged from outpatient surgeries. Furthermore, since both the Hospital IQR and Hospital OQR Programs are quality reporting programs, a hospital's performance on these measures is not tied to payment incentives.

Therefore, we invite public comment on how these programs could further encourage hospitals to improve discharge processes, such as by introducing measures currently in quality reporting programs into value-based purchasing to link outcomes to payment incentives. We are specifically interested in input on adopting measures which better represent the range of outcomes of interest to patients, including unplanned returns to the ED and receipt of observation services within 30 days of a patient's discharge from an inpatient stay.

We invite public comment on this topic.

C. Requirements for and Changes to the Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

Through the Hospital IQR Program, we strive to ensure that patients, along with their clinicians, can use information from meaningful quality measures to make better decisions about their healthcare. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, affordability, and equity of care while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with the Centers for Medicare & Medicaid Services (CMS) programs. In combination with other efforts across the Department of Health and Human Services (HHS), the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality, equitable, and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant interested parties to define measures in almost every care setting and currently measure some aspects of care for almost all Medicare beneficiaries. These measures assess clinical processes and outcomes, patient safety and adverse events, patient experiences with care, care coordination, and cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959);
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426);
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); and
- The FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to 42 CFR 412.140(g)(1) for our finalized measure retention policy. We first adopted these policies in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) and codified them in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59174 through 59175). Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited period is proposed and finalized. Measures are also retained unless we propose to remove, suspend, or replace the measures.

We are not proposing any changes to these policies in this proposed rule.

3. Removal of and Removal Factors for Hospital IQR Program Measures

We refer readers to 42 CFR 412.140(g)(2) and (3) for the Hospital IQR Program's policy regarding the factors CMS considers when removing measures from the program. We first adopted these factors in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) and codified them in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59174 through 59175). We are not proposing any changes to these policies in this proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We are not proposing any changes to these policies in this proposed rule. We also refer readers to the CMS National Quality Strategy that we launched in 2022, with the aims of promoting the highest quality outcomes and safest care for all individuals.[256]

To comply with statutory requirements that the Secretary of HHS make publicly available certain quality and efficiency measures that the Secretary is considering for adoption through rulemaking under Medicare,[257] the Consensus-Based Entity (CBE), currently Battelle, convenes the

[256] Centers for Medicare & Medicaid Services. (2022). What is the National Quality Strategy? Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[257] See section 1890A(a)(2) of the Social Security Act (42 U.S.C. 1395aaa–1(a)(2)).

Partnership for Quality Measurement (PQM), which is comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process. We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for more details on the updated pre-rulemaking measure reviews (PRMR) process, including measure endorsement and maintenance (E&M) process, for the purpose of providing multi-interested party input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the Hospital IQR Program.

5. Proposed New Measures for the Hospital IQR Program Measure Set

We are proposing to adopt seven new measures: (1) Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (2) Age Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment; (3) Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (4) Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (5) Hospital Harm—Falls with Injury eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; (6) Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; and (7) Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination. We provide more details on these proposals in the subsequent sections of the preamble, and details on the proposal for the Patient Safety Structural measure are in section IX.B.1.

a. Proposal To Adopt the Age Friendly Hospital Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

(1) Background

The U.S. population is aging rapidly, with nearly one in seven Americans at age 65 years or older in 2019.[258] In the next 10 years, one in five Americans is estimated to be over 65 years old, reaching 80.8 million by 2040.[259] As the population ages, care can become more complex,[260] with patients often developing multiple chronic conditions such as dementia, heart disease, arthritis, type 2 diabetes, and cancer.[261] These chronic conditions are among the nation's leading drivers of illness, disability, and healthcare costs.[262]

[258] Centers for Disease Control and Prevention. (September 2022). Promoting Health for Older Adults. Retrieved from: *https://www.cdc.gov/chronicdisease/resources/publications/factsheets/promoting-health-for-older-adults.htm.*

[259] Vespa, J., Armstrong, D.M., & Medina, L. (Rev Feb 2020). Demographic turning points for the United States: Population projections for 2020 to 2060. Washington, DC: U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau.

[260] Quiñones, A.R., Markwardt, S., & Botoseneanu, A. (2016). Multimorbidity combinations and disability in older adults. Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences, 71(6), 823–830.

[261] Centers for Disease Control and Prevention. (September 2022). Promoting Health for Older Adults. Retrieved from: *https://www.cdc.gov/chronicdisease/resources/publications/factsheets/promoting-health-for-older-adults.htm.*

[262] Centers for Disease Control and Prevention. (September 2022). Promoting Health for Older Adults. Retrieved from: *https://www.cdc.gov/chronicdisease/resources/publications/factsheets/promoting-health-for-older-adults.htm.*

Hospitals are increasingly faced with treating older patients who have complex medical, behavioral, and psychosocial needs that are often inadequately addressed by the current healthcare infrastructure.[263] The Centers for Disease Control and Prevention (CDC), and other interested parties, have estimated that over 60 percent of Medicare beneficiaries have two or more chronic conditions.[264] [265] To address the challenges of delivering care to older adults with multiple chronic conditions from a hospital and health system perspective, multiple organizations, including American College of Surgeons (ACS), the Institute for Healthcare Improvement (IHI), and the American College of Emergency Physicians, collaborated to identify and establish age-friendly initiatives based on evidence-based best practices that provide goal centered, clinically effective care for older patients.[266] [267] These organizations define age-friendly care as: (1) following an essential set of evidence-based practices; (2) causing no harm; and (3) aligning with ''What Matters'' [268] to the older adult and their family or other caregivers.[269] Based on these age-friendly initiatives and definition, these organizations have developed a framework comprised of a set of four evidence-based elements of high-quality care to older adults, called the ''4 Ms'': What Matters, Medication, Mentation, and Mobility.[270] The elements of the ''4 Ms'' help organize care for older adults wellness regardless of the number of chronic conditions, a person's culture, or their racial, ethnic, or religious background.[271]

The collective evidence from these age-friendly efforts demonstrates that hospitals should prioritize patient-centered care for aging patient populations with multiple chronic conditions. With CMS being the largest provider of healthcare coverage for the 65 years and older population, proposing a quality measure aimed at optimizing care for older patients, using a holistic approach to better serve the needs of this unique population, is timely. Although existing quality metrics have improved both the rate and reporting of clinical outcomes that are important to older individuals, these measures can be narrow in scope and may have limited long term effectiveness due to ceiling effects. We are therefore proposing to adopt an attestation-based structural measure, the Age Friendly Hospital measure, for the Hospital IQR Program, beginning with the CY 2025 reporting period/FY 2027 payment determination. This structural measure seeks to ensure that hospitals are reliably implementing the ''4 M's'', and thus providing evidence-based elements of high-quality care for all older adults.[272] The elements in the Age Friendly Hospital measure align with IHI's and Hartford Foundation national initiative for Age Friendly Systems in which many hospitals already participate.[273]

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27103 through 27109) we solicited public comments about the potential inclusion of two geriatric care measures in the Hospital IQR Program measure set. These two potential geriatric care measures focused on ensuring hospitals were committed to implementing surgical, and general hospital best practices, for geriatric populations. Public commenters were largely in support of both geriatric care measures (88 FR 59185 through 59193) and stated that measures focused on geriatric care would help a rapidly aging population with unique characteristics find the care they need. The two potential measures, Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032), were included in the ''2022 Measures Under Consideration List'' (MUC List) [274] and received significant support from the CBE, and it was recommended that the two measures be combined into one.[275] In response to CBE and public feedback, we are proposing this streamlined and combined version of the former two measures (88 FR 59185 through 59193). This structural measure applies a broad scope of evidence-based best practices, focused on goal centered, clinically effective care for older patients in the hospital inpatient setting.

We note that past comments have reflected concerns regarding structural measures because they do not explicitly link to improved outcomes. This is because there is no existing validation process confirming the accuracy of hospitals' responses to these types of measures. Despite this, structural measures, over time and in select circumstances, have certain advantages over other types of measures. Structural measures provide a way to address a new topic for which no outcome measure exists, such as the Age Friendly Hospital measure, the Hospital Commitment to Health Equity measure (87 FR 49191 through 49201), and the Maternal Morbidity structural measure (86 FR 45361 through 45365). In these examples, structural measures set a new expectation for the development of evidence-based programs and processes that will support improvements in these high impact areas. In the future, these structural measures can also be linked to new outcome measures or included in the Hospital Star Ratings Program.

(2) Overview of Measure

The Age Friendly Hospital measure assesses hospital commitment to improving care for patients 65 years or older receiving services in the hospital, operating room, or emergency department. This measure consists of five domains that address essential aspects of clinical care for older patients. Table IX.C.1 includes the five

[263] Boyd, C., Smith, C.D., Masoudi, F.A., Blaum, C.S., Dodson, J.A., Green, A.R., . . . & Tinetti, M.E. (2019). Decision making for older adults with multiple chronic conditions: executive summary for the American Geriatrics Society guiding principles on the care of older adults with multimorbidity. Journal of the American Geriatrics Society, 67(4), 665–673.

[264] Lochner KA, Cox CS. Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010. Prev Chronic Dis 2013;10:120137. DOI: *http://dx.doi.org/10.5888/pcd10.120137.*

[265] Salive, M.E. (2013). Multimorbidity in older adults. Epidemiologic reviews, 35(1), 75–83.

[266] American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. (2012). Guiding principles for the care of older adults with multimorbidity: an approach for clinicians. *Journal of the American Geriatrics Society, 60*(10), E1–E25.

[267] Boyd, C., Smith, C.D., Masoudi, F.A., Blaum, C.S., Dodson, J.A., Green, A.R., . . . & Tinetti, M.E. (2019). Decision making for older adults with multiple chronic conditions: executive summary for the American Geriatrics Society guiding principles on the care of older adults with multimorbidity. Journal of the American Geriatrics Society, 67(4), 665–673.

[268] Tinetti, M. (January 2019). [Blog] How focusing on What Matters simplifies complex care for older adults. Institute for Healthcare Improvement. Available at: *https://www.ihi.org/insights/how-focusing-what-matters-simplifies-complex-care-older-adults.*

[269] Institute for Healthcare Improvement. (2022). Age-friendly health systems: Guide to using the 4Ms in the care of older adults in hospitals and ambulatory practices. Available at: *https://forms.ihi.org/hubfs/IHIAgeFriendlyHealthSystems_GuidetoUsing4MsCare.pdf.*

[270] Ibid.

[271] Ibid.

[272] Institute for Healthcare Improvement. (2022). Age-friendly health systems: Guide to using the 4Ms in the care of older adults in hospitals and ambulatory practices. Available at: *https://forms.ihi.org/hubfs/IHIAgeFriendlyHealthSystems_GuidetoUsing4MsCare.pdf.*

[273] Institute for Healthcare Improvement. (2022). Age-friendly health systems: Guide to using the 4Ms in the care of older adults in hospitals and ambulatory practices. Available at: *https://forms.ihi.org/hubfs/IHIAgeFriendlyHealthSystems_GuidetoUsing4MsCare.pdf.*

[274] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[275] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

attestation domains and corresponding attestation statements.

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TABLE IX.C-1. THE AGE FRIENDLY HOSPITAL MEASURE'S FIVE DOMAIN ATTESTATIONS

Attestation Domains	Attestation Statements: Attest "yes" or "no" to each element. (Note: Affirmative attestation of all elements within a domain would be required for the hospital or health system to receive a point for that domain)
Domain 1: Eliciting Patient Healthcare Goals This domain focuses on obtaining patient's health related goals and treatment preferences which will inform shared decision making and goal concordant care.	**(A)** Established protocols are in place to ensure patient goals related to healthcare (health goals, treatment goals, living wills, identification of healthcare proxies, advance care planning) are obtained/reviewed and documented in the medical record. These goals are updated before major procedures and upon significant changes in clinical status.
Domain 2: Responsible Medication Management This domain aims to optimize medication management through monitoring of the pharmacological record for drugs that may be considered inappropriate in older adults due to increased risk of harm.	**(A)** Medications are reviewed for the purpose of identifying potentially inappropriate medications (PIMs) for older adults as defined by standard evidence-based guidelines, criteria, or protocols. Review should be undertaken upon admission, before major procedures, and/or upon significant changes in clinical status. Once identified, PIMS should be considered for discontinuation, and/or dose adjustment as indicated.
Domain 3: Frailty Screening and Intervention This domain aims to screen patients for geriatric issues related to frailty including cognitive impairment/delirium, physical function/mobility, and malnutrition for the purpose of early detection and intervention where appropriate.	**(A)** Patients are screened for risks regarding mentation, mobility, and malnutrition using validated instruments ideally upon admission, before major procedures, and/or upon significant changes in clinical status. **(B)** Positive screens result in management plans including but not limited to minimizing delirium risks, encouraging early mobility, and implementing nutrition plans where appropriate. These plans should be included in discharge instructions and communicated to post-discharge facilities. **(C)** Data are collected on the rate of falls, decubitus ulcers, and 30-day readmission for patients > 65. These data are stratified by demographic and/or social factors. **(D)** Protocols exist to reduce the risk of emergency department delirium by reducing length of emergency department stay with a goal of transferring a targeted percentage of older patients out of the emergency department within 8 hours of arrival and/or within 3 hours of the decision to admit.
Domain 4: Social Vulnerability This domain seeks to ensure that hospitals recognize the importance of social vulnerability screening of older adults and have systems in place to ensure that social issues are identified and addressed as part of the care plan.	**(A)** Older adults are screened for geriatric specific social vulnerability including social isolation, economic insecurity, limited access to healthcare, caregiver stress, and elder abuse to identify those who may benefit from care plan modification. The assessments are performed on admission and again prior to discharge. **(B)** Positive screens for social vulnerability (including those that identify patients at risk of mistreatment) are addressed through intervention strategies. These strategies should include appropriate referrals and resources for patients upon discharge.
Domain 5: Age-Friendly Care Leadership This domain seeks to ensure consistent quality of care for older adults through the identification of an age friendly champion and/or interprofessional committee tasked with ensuring compliance with all components of this measure.	**(A)** Our hospital designates a point person and/or interprofessional committee to specifically ensure age friendly care issues are prioritized, including those within this measure. This individual or committee oversees such things as quality related to older patients, identifies opportunities to provide education to staff, and updates hospital leadership on needs related to providing age friendly care. **(B)** Our hospital compiles quality data related to the Age Friendly Hospital measure. These data are stratified by demographic and/or social factors and should be used to drive improvement cycles.

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(3) Measure Alignment to Strategy

This measure aligns with our efforts under the CMS National Quality Strategy priority area of ''Equity and Engagement'' that seeks to advance equity and whole-person care as well as to engage individuals and communities to become partners in their care.[276] This measure additionally aligns with the CMS National Quality Strategy priority area of ''Outcomes and Alignment'' that aims to improve quality and health outcomes across the care journey including the objective to improve quality in high-priority clinical areas and supportive services.[277]

The domains and attestation statements in this measure span the breadth of the clinical care pathway and, together, provide a framework for optimal care of the older adult patient. More specifically, the domains focus on patient goals, medication management, frailty, social vulnerability, and leadership/governance commitment. This structural measure identifies the best evidence-based practices for hospital leadership, operations, and high reliability across each domain, particularly with the unavailability of more direct metrics related to each of the domains. In addition, this measure complements current patient safety reporting, supports hospitals in improving the quality of care for a complex patient population, and furthers our commitment to advancing health equity among the diverse older communities served by participants in CMS programs.

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of the preamble of this proposed rule for details on the PRMR process including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List),[278] [279] including the Age

[276] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[277] Ibid.

[278] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under

Continued

Friendly Hospital measure (MUC2023–219), and to vote on a recommendation with regard to use of this measure.

The PRMR Hospital Recommendation Group for the Age Friendly Hospital measure did not reach consensus and did not recommend including this measure in the Hospital IQR Program either with or without conditions. Eleven of the sixteen members of the group recommended adopting the measure into the Hospital IQR Program without conditions; zero members recommended adoption with conditions; five committee members voted not to recommend the measure for adoption. No voting category reached 75 percent or greater, including the combination of the recommend and the recommend with conditions categories. Thus, the committee did not reach consensus and did not recommend including this measure in the Hospital IQR Program either with or without conditions.

Several PRMR Hospital Committee members applauded the intent of this measure and the push toward transparency and consistency in reporting, noting these types of measures signal to hospital leadership and governance the importance of prioritizing initiatives and implementing frameworks outlined in the measure, highlighting how important this specific measure is for prioritizing improving care for older patients.[280] PRMR Hospital Committee members also commented on the measure's flexibility regarding screening tools noting it was not overly prescriptive.[281] Several PRMR Hospital Committee members noted concerns about structural measures in general and whether they drive action.[282] Specifically, PRMR Hospital Committee members expressed concerns that the measure domains were not tightly scoped enough to drive discrete action. We acknowledge the concerns identified by the PRMR Hospital Committee members. Nevertheless, we have concluded that this measure does support reliable practices that drive change, transparent reporting, and prioritization of resources to implement these best practices. The measure was developed from a large collaborative that has evaluated the elements incorporated into these domains across many different geographic locations, hospital sizes, and patient demographics. We also refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59186) where we discussed previous CBE review of the Geriatric Hospital and Geriatric Surgical measures, which were combined by the measure developer based on previous CBE recommendations to create the Age Friendly Hospital measure. As previously discussed, this structural measure plays a role in establishing the foundation for health outcome quality measures and that this particular measure would support improvements in quality of care in hospitals participating in the Hospital IQR Program by filling gaps in care management for older adults.

(b) Measure Endorsement

The measure has not been submitted for CBE endorsement at this time. We are proposing in this preamble of this proposed rule to adopt this measure into the Hospital IQR Program despite the measure not yet being endorsed by the CBE. Although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. During measure endorsement, the CBE considers whether a measure ''is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and is consistent across types of health care providers, including hospitals and physicians (section 1890(b)(2)(A) and (B) of the Act).

We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic. We are adopting this measure pursuant to section 1886(b)(3)(B)(viii)(IX)(bb) of the Act. As previously discussed, we have determined this an appropriate topic for a measure to be adopted absent endorsement because this measure is important for establishing a foundation for future health outcome measures and that this measure provides a framework of best practices for delivering care to older adults with multiple chronic conditions from a hospital and health system perspective.

(5) Measure Calculation

The Age Friendly Hospital measure consists of five domains, each representing a separate domain commitment. Hospitals or health systems would need to evaluate and determine whether they can affirmatively attest to each domain, some of which have multiple attestation statements, for each hospital reported under their CMS certification number (CCN). For a hospital or a health system to affirmatively attest to a domain, and receive a point for that domain, a hospital or health systems would evaluate and determine whether it engaged in each of the elements that comprise the domain (see Table IX.C.1), for a total of five possible points (one point per domain).

A hospital or health system would not be able to receive partial points for a domain. For example, for Domain 3 (''Frailty Screening and Intervention''), a hospital or health system would evaluate and determine whether their hospital or health system's processes meet each of the corresponding attestation statements described in (A), (B), (C), and (D) (see Table IX.C.1). If the hospital or health system's processes meet all four attestation statements in Domain 3, the hospital or health system would receive a point for that domain. However, if the hospital could only affirmatively attest to (B) and (C), for example, then no points could be earned for Domain 3. We note that because the Hospital IQR Program is a pay-for-reporting program, hospitals would receive credit for the reporting of their measure results regardless of their responses to the attestation questions.

For more details on the measure specifications for the Hospital IQR Program, we refer readers to the Web-Based Data Collection tab under the Hospital IQR Program measures page on QualityNet at: *https://qualitynet.cms.gov/inpatient/iqr/measures#tab1*

Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[279] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[280] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Final MUC Recommendation Report. Available at: *https://p4qm.org/PRMR.*

[281] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Final MUC Recommendation Report. Available at: *https://p4qm.org/PRMR.*

[282] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Final MUC Recommendation Report. Available at: *https://p4qm.org/PRMR.*

(or other successor CMS designated websites).

(6) Data Submission and Reporting

Hospitals and/or health systems are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System. We are proposing the mandatory reporting of this measure beginning with the CY 2025 reporting period/FY 2027 payment determination. We refer readers to section IX.C.9. of the preamble of this proposed rule for more details on our data submission and deadline requirements for structural measures. Specifications for the measure will also be posted on the QualityNet web page at: *https://qualitynet.cms.gov/inpatient/iqr/measures#tab1* (or other successor CMS designated websites).

We refer readers to section IX.C.9. of this proposed rule for our previously finalized structural measure reporting and submission requirements. We invite public comment on our proposal to adopt the Age Friendly Hospital measure beginning with CY 2025 reporting period/FY 2027 payment determination.

b. Proposal To Adopt Two Healthcare-Associated Infection (HAI) Measures Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

Healthcare-associated infections (HAIs) are a major cause of illness and death in hospitals, posing a significant threat to patient safety. One in 31 hospital patients in the U.S. have a HAI at any given time, totaling about 687,000 cases per year.[283] The CDC estimated that about 72,000 patients die from HAIs per year.[284] HAIs not only put patients at risk, but also increase the hospitalization days required for patients and add considerably to healthcare costs. The CDC estimates that HAIs cost the U.S. healthcare system $28.4 billion per year.[285] Statistics on preventability vary but suggest that 55–70 percent of HAIs could be prevented through practices including hand hygiene, cleaning surfaces with an appropriate antiseptic, and wearing gowns and gloves.[286]

Given the high risk to patient safety, we previously adopted the National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) and NHSN Central Line-Associated Bloodstream Infection (CLABSI) measures in various quality reporting programs that measure the annual risk-adjusted standardized infection ratio (SIR) among adult inpatients. The measures were originally introduced in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51617 through 51618) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50200 through 50202). In the FY 2014 IPPS/LTCH PPS final rule, the CAUTI and CLABSI measures were then moved into the Hospital-Acquired Condition (HAC) Reduction Program (78 FR 50717) and the Hospital Value-Based Purchasing (VBP) Program (78 FR 50681 through 50687). The CAUTI and CLABSI measures used in these programs include most major inpatient care wards at acute care hospitals, including inpatient psychiatric facilities, hospice, inpatient acute care facilities, and inpatient rehabilitation facilities. However, locations mapped as oncology wards have not been included.

Patients with cancer are especially vulnerable to developing HAIs. Chemotherapy, a common treatment for patients with cancer, can weaken patients' immune systems and leave them vulnerable to opportunistic infections.[287] Cancer treatment may also require major surgeries or invasive devices, which can act as another vector for infections.[288] It is estimated that 10.5 percent of patients undergoing major cancer surgery contract a HAI, compared to only three percent of patients undergoing elective surgeries.[289] Researchers from the same study also found that patients undergoing major cancer surgery who contracted a HAI were significantly more likely to die in the hospital than patients who did not contract a HAI.[290] In another study, researchers found that developing a HAI was linked to higher costs of care and longer lengths of stay for patients with cancers of the lip, oral cavity, and pharynx.[291] Therefore in the FY 2013 IPPS/LTCH PPS final rule, beginning with the FY 2014 program year, we adopted the CAUTI and CLABSI measures in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (77 FR 53557 through 53559).

While many oncology services have transitioned to outpatient settings, acute care hospitals continue to specialize in the treatment of certain types of patients with cancer, for example, patients who have received a hematopoietic stem cell transplant and patients who have febrile neutropenia.[292] Based on an internal CMS analysis, in 2019 there were 321,961 Medicare beneficiaries with a primary diagnosis of cancer who received some portion of their care in an inpatient hospital setting. Within these inpatient settings, the majority of Medicare beneficiaries with a primary diagnosis of cancer received their care at National Cancer Institute (NCI)-designated hospitals or other acute care hospitals, while only about four percent of Medicare beneficiaries received care at PPS-exempt cancer hospitals (PCHs). Additionally, based on internal CMS analysis, a portion of these Medicare beneficiaries who received care at a PCH also received at least some of their inpatient care at non-PCHs (NCI-affiliated or other hospitals).

The Biden-Harris administration's Cancer Moonshot Program has put a renewed focus on improving outcomes for patients with cancer.[293] Under this initiative, we seek to ensure that patients with cancer treated at hospitals reporting to the Hospital IQR Program are able to benefit from public reporting of hospital safety data and choose the best provider for their needs. We are proposing to adopt the Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations and the Central Line-Associated Bloodstream Infection (CLABSI)

[283] CDC. (2023). HAI Data Portal. Available at: *https://www.cdc.gov/hai/data/portal/index.html.*

[284] Ibid.

[285] CDC. (2021). Health Topics—Healthcare-associated Infections (HAI). Available at: *https://www.cdc.gov/policy/polaris/healthtopics/hai/index.html#:~:text=HAIs%20in%20U.S.%20hospitals%20have,least%20%2428.4%20billion%20each%20year.*

[286] Bearman, G., Doll, M., Cooper, K. et al. Hospital Infection Prevention: How Much Can We Prevent and How Hard Should We Try? Curr Infect Dis Rep 21, 2. (2019). *https://doi.org/10.1007/s11908-019-0660-2.*

[287] da Silva R, Casella T. (2022). Healthcare-associated infections in patients who are immunosuppressed due to chemotherapy treatment: a narrative review. J Infect Dev Ctries 16:1784–1795. doi: 10.3855/jidc.16495.

[288] Biscione A, Corrado G, Quagliozzi L, Federico A, Franco R, Franza L, Tamburrini E, Spanu T, Scambia G, Fagotti A. Healthcare associated infections in gynecologic oncology: clinical and economic impact. Int J Gingerol Cancer. 2023 Feb 6;33(2):278–284. doi: 10.1136/ijgc-2022–003847. PMID: 36581487.

[289] Sammon, J., Trinh, V.Q., Ravi, P., Sukumar, S., Gervais, M.-K., Shariat, S.F., Larouche, A., Tian, Z., Kim, S.P., Kowalczyk, K.J., Hu, J.C., Menon, M., Karakiewicz, P.I., Trinh, Q.-D. and Sun, M. (2013), Health care-associated infections after major cancer surgery. Cancer, 119: 2317–2324. *https://doi.org/10.1002/cncr.28027.*

[290] Ibid.

[291] Sankaran SP, Villa A, Sonis S. Healthcare-associated infections among patients hospitalized for cancers of the lip, oral cavity and pharynx. Infect Prev Pract. 2021 Jan 13;3(1):100115. doi: 10.1016/j.infpip.2021.100115. PMID: 34368735; PMCID: PMC8336044.

[292] CDC. (2019). Basic Infection Control and Prevention Plan for Outpatient Oncology Settings. *https://www.cdc.gov/hai/settings/outpatient/basic-infection-control-prevention-plan-2011/index.html.*

[293] The White House. Cancer Moonshot. *https://www.whitehouse.gov/cancermoonshot/.*

Standardized Infection Ratio Stratified for Oncology Locations (hereinafter referred to as the CAUTI-Onc measure and CLABSI-Onc measure, respectively), beginning with the CY 2026 reporting period/FY 2028 payment determination. These measures would supplement, not duplicate, the existing hospital CAUTI and CLABSI measures, as the original hospital CAUTI and CLABSI measures look at hospital inpatients except for those in oncology wards, and the CAUTI-Onc and CLABSI-Onc measures look only at patients in oncology wards. Our proposals to adopt the CAUTI-Onc and CLABSI-Onc measures are part of our renewed effort to improve patient safety. We refer readers to the proposal to adopt the Patient Safety Structural measure in section IX.B.1. for more information.

(1) Proposal To Adopt the CAUTI-Onc Measure Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

(a) Background

Urinary tract infections (UTIs) are a common type of HAI and come with many risks to patients. About 12–16 percent of adult patients in inpatient hospitals will have a urinary catheter at some point during their hospital stay, and almost all healthcare associated UTIs are introduced through instrumentation in the urinary tract.[294] Furthermore, each day the indwelling urinary catheter remains, a patient has between a three and seven percent increased risk of acquiring a catheter-associated urinary tract infection.[295] Based on data from the NHSN, the CDC reported that among the 3,780 general acute care hospitals that reported data in 2022, there were 20,237 CAUTIs in that year.[296]

CAUTIs can lead to many negative consequences for patients including cystitis, pyelonephritis, gram-negative bacteremia, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis.[297] Other consequences of CAUTIs include prolonged hospital stays, higher healthcare costs, and an increased likelihood of mortality.[298]

However, CAUTIs can often be prevented by following guidelines for urinary catheter use, insertion, and maintenance. At a large academic hospital system, a study investigated the effects of implementing a CAUTI prevention bundle in the intensive care unit (ICU). Prevention practices in this bundle included reducing unnecessary catheter use, following proper catheter maintenance, and ordering a urine culture only when warranted by a clear indication. The research team also updated the electronic health record (EHR) system to support compliance with these prevention guidelines. Researchers found that the CAUTI rates in the ICU decreased from 6.0 CAUTIs per 1,000 urinary catheter days to 0.0. The rest of the hospital then implemented the CAUTI prevention bundle, leading to a decrease in CAUTI rates from 2.0 cases per 1,000 catheter days to 0.6 cases per 1,000 catheter days.[299]

In another study, nurses at a large urban teaching hospital implemented CAUTI prevention protocols, including removing catheters from patients no longer needing them and finding alternatives to indwelling urinary catheters. As a result of this initiative, catheter days decreased by 11.8 percent and CAUTI rates declined by 38 percent.[300] More information on the prevention of CAUTIs is available in the CDC's Guideline for Prevention of Catheter-associated Urinary Tract Infections, including recommendations regarding who should receive a catheter, catheter insertion, proper insertion techniques, maintenance, quality improvement, and surveillance.[301]

To encourage the use of best practices for urinary catheters and reduce the incidence of CAUTIs, we previously adopted the CAUTI measure (CBE #0138) to several quality reporting and value-based payment programs, including the Hospital IQR, Hospital VBP, and HAC Reduction Programs (76 FR 51617 through 51618, 78 FR 50681 through 50687, and 78 FR 50717, respectively) as discussed earlier. We adopted the measure as part of the HHS Action Plan to Prevent HAIs, as this measure was included among the prevention metrics established in the plan which is available at: *https://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html.* Eventually, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), we removed the CAUTI measure from the Hospital IQR Program beginning with the CY 2019 reporting period/FY 2021 payment determination to streamline reporting through the HAC Reduction Program.

As noted earlier, the CAUTI measure used in the HAC Reduction and Hospital VBP Programs does not include inpatients in cancer wards. Because patients with cancer are especially vulnerable to developing HAIs like CAUTIs,[302] it is important to implement quality reporting for patients with cancer, as we have done in adopting the CAUTI measure in the PCHQR Program. Significant associations have been found between UTIs and post-surgery complications, longer hospitalizations, and higher hospital costs among patients with cancer [303] and post-surgery CAUTI incidence has been found to be as high as 12.5 percent in specific cancer populations.[304] Therefore, it is important to address the needs of this high-risk population and adopt the CAUTI-Onc measure to the Hospital IQR Program. The adoption of this measure would also provide more data to compare CAUTI rates between PCHs and non-PCHs.

(b) Overview of Measure

We are proposing to adopt the CAUTI-Onc measure for the Hospital IQR Program beginning with the CY 2026 reporting period/FY 2028 payment determination. The purpose of this

[294] CDC. (2024). Urinary Tract Infection (Catheter-Associated Urinary Tract Infection [CAUTI] and Non-Catheter-Associated Urinary Tract Infection [UTI]) Events. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf.*

[295] Ibid.

[296] CDC. (2022). Antibiotic Resistance & Patient Safety Portal: Catheter-Associated Urinary Tract Infections. Available at: *https://arpsp.cdc.gov/profile/nhsn/cauti.*

[297] CDC. (2024). Urinary Tract Infection (Catheter-Associated Urinary Tract Infection [CAUTI] and Non-Catheter-Associated Urinary Tract Infection [UTI]) Events. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf.*

[298] Ibid.

[299] Sampathkumar, P., Barth, J. W., Johnson, M., Marosek, N., Johnson, M., Worden, W., Lembke, J., Twing, H., Buechler, T., Dhanorker, S., Keigley, D., & Thompson, R. (2016). Mayo Clinic Reduces Catheter-Associated Urinary Tract Infections Through a Bundled 6–C Approach. Joint Commission journal on quality and patient safety, 42(6), 254–261. *https://doi.org/10.1016/s1553-7250(16)42033-7.*

[300] Baker, Susan BSN, RN; Shiner, Darcy BSN, RN; Stupak, Judy MSN, RN, CNRN; Cohen, Vicki MSN, RN, CNRN; Stoner, Alexis BSN, RN. Reduction of Catheter-Associated Urinary Tract Infections: A Multidisciplinary Approach to Driving Change. Critical Care Nursing Quarterly 45(4):p 290–299, October/December 2022. | DOI: 10.1097/CNQ.0000000000000429.

[301] CDC. (2019). Guideline for Prevention of Catheter-Associated Urinary Tract Infections. Available at: *https://www.cdc.gov/infectioncontrol/guidelines/cauti/index.html.*

[302] da Silva R, Casella T. (2022). Healthcare-associated infections in patients who are immunosuppressed due to chemotherapy treatment: a narrative review. J Infect Dev Ctries 16:1784–1795. doi: 10.3855/jidc.16495.

[303] Chan JY, Semenov YR, Gourin CG. Postoperative urinary tract infection and short-term outcomes and costs in head and neck cancer surgery. Otolaryngol Head Neck Surg. 2013 Apr;148(4):602–10. doi: 10.1177/0194599812474595. Epub 2013 Jan 24. PMID: 23348871.

[304] Mercadel, A.J., Holloway, S.B., Saripella, M., & Lea, J.S. (2023). Risk factors for catheter-associated urinary tract infections following radical hysterectomy for cervical cancer. American journal of obstetrics and gynecology, 228(6), 718.e1–718.e7. *https://doi.org/10.1016/j.ajog.2023.02.019.*

measure is to encourage the use of best practices for urinary catheters as set by the CDC and to reduce the incidence of CAUTIs for patients with cancer. To report this measure, hospitals will need to verify that all locations, including those housing oncology patients, are correctly mapped in NHSN.

Reducing CAUTI incidence through the adoption of this measure could lead to improved cancer patient outcomes, including reduced morbidity and mortality, less need for antimicrobials, and reduced patient length of stays and medical costs.[305]

(c) Measure Alignment to Strategy

The proposal to adopt the CAUTI-Onc measure supports the CMS National Quality Strategy priority area of ''Safety and Resiliency.'' [306] Specifically, this supports our safety goal to ''achieve zero preventable harm,'' and to expand the collection and use of safety indicator data across programs for key areas to improve tracking and show progress toward reducing harm. The adoption of this measure additionally supports the ''Outcomes and Alignment'' priority area in the CMS National Quality Strategy by collaborating with other federal agencies, namely the CDC, to promote alignment in quality measurement and close the existing reporting gap among vulnerable patients with cancer in inpatient settings.[307] This proposal to adopt the CAUTI-Onc measure not only supports two of the CMS National Quality Strategy priority areas, it also supports the Biden-Harris Administration's Cancer Moonshot program that aims to improve outcomes for patients with cancer.

(d) Pre-Rulemaking Process and Measure Endorsement

(i) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of the preamble of this proposed rule for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List), including the CAUTI-Onc measure (MUC2023–220),[308] [309] and to vote on a recommendation with regard to use of this measure recommendation with regard to use of this measure.[310]

The PRMR Hospital Committee reached consensus and recommended including this measure in the Hospital IQR Program with conditions. Fourteen members of the group recommended adopting the measure into the Hospital IQR Program without conditions; four members recommended adoption with conditions; and one committee member voted not to recommend the measure for adoption. Taken together, 94.7 percent of the votes recommended this measure in the Hospital IQR Program with conditions.[311]

Four members of the voting committee recommended the adoption of this measure into the Hospital IQR Program with the first condition being that CMS consider expanding the reporting period. This would increase the patient volume included in the denominator and increase precision. We have reviewed this recommendation and concluded that expanding the reporting period would result in a critical loss in the ability to observe changes in the SIR over time. Obscuring any observable changes in the SIR would degrade the measure's ability to assess prevention efforts and further drive quality improvement. Therefore, we are proposing this measure for adoption without the modification suggested by four committee members in order to preserve the measure's ability to observe changes in the SIR more quickly.

The second condition the PRMR Hospital Committee recommended for the Hospital IQR Program was that the measure should evaluate data by oncology unit type, such as hematology-oncology versus solid organ.[312] We acknowledge this condition and may consider it for future rulemaking. We are proposing to adopt the CAUTI-Onc measure in the Hospital IQR Program having taken into consideration the conditions raised by the PRMR Hospital Committee.

The measure received strong support from the committee as it addresses an important patient safety concern. During the PRMR Hospital Committee's discussion, some expressed concern about the burden of manual abstraction. Others asked about the measure's validity, and whether the measure should include risk adjustments when HAIs are an issue across the board.

(ii) Measure Endorsement

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees use to evaluate measures and whether they meet endorsement criteria. The CAUTI measure was most recently submitted to the CBE for endorsement review in the Spring 2019 cycle (CBE #0138) and was endorsed on October 23, 2019.[313] In the submission of the CAUTI-Onc measures to the 2023 MUC list, the CDC provided additional oncology-only reliability testing based on existing data submitted to the CDC's NHSN. Because the CAUTI-Onc measure has the same specifications as the CAUTI measure, with the only difference being that it is stratified for oncology locations, additional endorsement of the oncology specific locations is not necessary. The calculations pertinent to those locations are inherently part of the endorsement performed for the CAUTI measure, and the measure (*i.e.* numerator/denominator) is endorsed across all inpatient hospital settings, including oncology locations. The calculation of the SIR includes and accounts for the location of the patient within the facility. The CDC will incorporate information on the stratification by oncology patients during the regularly scheduled measure maintenance re-endorsement process.

(e) Measure Specifications

For this measure, the NHSN calculates the quarterly risk-adjusted SIR of CAUTIs among inpatients at acute care hospitals who are in oncology

[305] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[306] CMS National Quality Strategy. (2023). Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[307] Ibid.

[308] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[309] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[310] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf.*

[311] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Final MUC Recommendation Report. Available at: *https://p4qm.org/PRMR.*

[312] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/PRMR.*

[313] Battelle—Partnership for Quality Measurement. NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure. Available at: *https://p4qm.org/measures/0138.*

wards.[314] The CDC then calculates the SIR using all four quarters of data from the reporting period year, which CMS uses for performance calculation and public reporting purposes. The CDC defines an oncology ward as an area for the evaluation and treatment of patients with cancer. For more details, we refer readers to the CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations document.[315]

The numerator is the number of annually observed CAUTIs among acute care hospital inpatients in oncology wards. The denominator is the number of annually predicted CAUTIs among acute care hospital inpatients in oncology wards. By dividing the number of observed CAUTIs by the number of predicted CAUTIs, the SIR compares the actual number of cases to the expected number of cases. However, this does not preclude SIRs from being ranked. The SIR is calculated when there is at least one predicted CAUTI, to achieve a minimum level of precision.[316]

The measure requires a facility to have at least one predicted CAUTI before calculating the SIR because the precision of a facility's CAUTI rate can vary, especially in low volume hospitals. For this reason, the NHSN calculates the SIR instead of reporting the CAUTI rate directly. A facility's SIR is not meant to be compared directly to that of another facility. Rather, the primary role of the SIR is to compare a facility's CAUTI rate to the national rate after adjusting for facility- and patient-level risk factors.[317]

The numerator and denominator exclude the following because they are not considered indwelling catheters by NHSN definitions: suprapubic catheters, condom catheters, ''in and out'' catheters, and nephrostomy tubes. If a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.[318]

The SIR also adjusts for various facility and patient-level factors that contribute to HAI risk within each facility. For more information on the risk adjustment methodology please reference the CDC website at: *https://www.cdc.gov/nhsn/2022rebaseline/index.html.*

(f) Data Submission and Reporting

We are proposing to collect data for the CAUTI-Onc measure via the NHSN, consistent with the current approach for HAI reporting for the HAC Reduction and Hospital VBP Programs. The NHSN is a secure, internet-based surveillance system maintained and managed by the CDC and provided free of charge to providers. To report to the NHSN, hospitals must first agree to the NHSN Agreement to Participate and Consent form, which specifies how NHSN data will be used, including fulfilling CMS's quality measurement reporting requirements for NHSN data.[319]

Beginning in 2012, hospitals participating in the Hospital IQR Program began reporting CAUTIs in all adult, pediatric, and neonatal intensive care locations followed by reporting all adult and pediatric medical, surgical, and medical/surgical wards in 2015 using NHSN. According to a 2022 CDC report, 3,780 hospitals are reporting CAUTI data to NHSN; of these, 478 hospitals reported CAUTI data from at least one oncology location.[320] We anticipate that because most of the hospitals which would begin to report the CAUTI-Onc measure for the Hospital IQR Program are already reporting via NHSN for CAUTI in other locations as well as other measures, they have already set up an account. Hospitals currently reporting CAUTI must verify that locations housing oncology patients are correctly mapped as an oncology location based on NHSN's location mapping guidance for accurate event location attribution.

Hospitals would report their data for the CAUTI-Onc measure on a quarterly basis for the purposes of Hospital IQR Program requirements. Presently, hospitals report CAUTI data to the NHSN monthly and the SIR is calculated on a quarterly basis. Under the data submission and reporting process, hospitals would collect the numerator and denominator for the CAUTI-Onc measure each month and submit the data to the NHSN. The data from all 12 months would be calculated into quarterly reporting periods which would then be used to determine the SIR for CMS performance calculation and public reporting purposes. We refer readers to the NHSN website for further information about NHSN reporting requirements. We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59141) for information on data submission and reporting requirements for our most recent updates to data submission and reporting requirements for measures submitted via the CDC NHSN.

We invite public comment on our proposal to adopt the CAUTI-Onc measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

(2) Proposal To Adopt the CLABSI-Onc Measure Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

(a) Background

Central venous catheters (CVCs) are a crucial aspect of hospital care for administering medications, fluids, and nutrients to patients, as well as running medical tests.[321] However, they also carry the risk of introducing infections, referred to as central line-associated bloodstream infections (CLABSIs).[322] CLABSIs are a leading cause of HAIs and are associated with increased morbidity and mortality, prolonged hospitalization, and increased costs.[323]

According to one study, the development of bloodstream infections (BSIs) after CVC insertion was associated with longer hospital stays of on average seven additional days and a three times higher risk of death during the patient's hospital stay.[324] Additionally, a single CLABSI episode

[314] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[315] CDC. (2023). CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/15locationsdescriptions_current.pdf.*

[316] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[317] CDC. (2022). NHSN SIR Guide. Available at: *https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf.*

[318] Battelle—Partnership for Quality Measurement. NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure. Available at: *https://p4qm.org/measures/0138.*

[319] CDC. (2023). FAQs About NHSN Agreement to Participate and Consent. Available at: *https://www.cdc.gov/nhsn/about-nhsn/faq-agreement-to-participate.html.*

[320] CDC. (2022). National and State Healthcare-associated Infections Progress Report. Available at: *https://www.cdc.gov/hai/data/portal/progress-report.html.*

[321] Medical News Today. (2023). What are central venous catheters? Available at: *https://www.medicalnewstoday.com/articles/central-venous-catheters.*

[322] CDC. (2011). Central Line-associated Bloodstream Infections: Resources for Patients and Healthcare Providers. Available at: *https://www.cdc.gov/hai/bsi/clabsi-resources.html#print.*

[323] Novosad, S.A., Fike, L., Dudeck, M.A., Allen-Bridson, K., Edwards, J.R., Edens, C., Sinkowitz-Cochran, R., Powell, K., & Kuhar, D. (2020). Pathogens causing central-line-associated bloodstream infections in acute-care hospitals-United States, 2011–2017. *Infection control and hospital epidemiology, 41*(3), 313–319. *https://doi.org/10.1017/ice.2019.303.*

[324] Brunelli, S.M., Turenne, W., Sibbel, S., Hunt, A., Pfaffle, A. (2016). Clinical and economic burden of bloodstream infections in critical care patients with central venous catheters. *Journal of Critical Care, 35,* 69–74. *https://doi.org/10.1016/j.jcrc.2016.04.035.*

costs hospitals an estimated $48,108 on average.[325] While the CLABSI SIR has declined by 16 percent since 2015, CLABSIs still remain prevalent.[326] Based on data from the NHSN, the CDC reported that among the 3,728 general acute care hospitals that reported data in 2022, there were 23,389 CLABSIs in that year.[327]

In one study conducted on a group of academic medical centers across a three-year period, the overall CLABSI rate was 1.73 cases per 1,000 central-line days.[328] Another study, retrospectively conducted on patients with a CVC in four U.S. hospitals within the same health system, found that patients with a CVC who developed a CLABSI had a 36.6 percent higher likelihood of mortality, and 37 percent higher chance of being readmitted compared to patients who did not develop a CLABSI. The study also found that the average hospital length of stay in patients who developed a CLABSI increased by two days when compared to patients without a CLABSI.[329]

Following evidence-based guidelines when inserting and maintaining central lines can help prevent the occurrence of CLABSIs.[330] Proper central line insertion practices include applying skin antiseptic, ensuring proper hand hygiene, using sterile barrier precautions, and ensuring the skin preparation agent has dried completely before insertion.[331] One study of 30 long-term acute care hospitals found that adoption of a catheter maintenance bundle led to the CLABSI rate decreasing by 29 percent.[332] In another study, researchers implemented the standard CDC bundle along with additional measures in a large acute care hospital. As a result, the CLABSI rate decreased by 68 percent from 2013 to 2017.[333] Despite a large body of evidence indicating that adopting a central line bundle decreases CLABSI rates, adoption of these best practices remains inconsistent. A systematic review of the available literature on hospital adherence to the CDC's central line bundle checklist found that none of the medical facilities in the studies followed all elements of the bundle, and compliance rates remained low in follow-up studies.[334] For more information on the standard CDC bundle, we refer readers to the Guidelines for the Prevention of Intravascular Catheter-Related Infections.[335]

To encourage adherence to best practices for central line use and to reduce the incidence of CLABSIs, we previously adopted the CLABSI measure (CBE #0139) to several quality reporting and value-based payment programs, including the Hospital IQR, Hospital VBP, and HAC Reduction Programs (75 FR 50200 through 50202, 78 FR 50681 through 50687, and 78 FR 50717, respectively) as discussed earlier. We adopted the measure as part of the HHS Action Plan to Prevent HAIs, as this measure was included among the prevention metrics established in the plan which is available at: *https://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html.* In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), we removed the CLABSI measure from the Hospital IQR Program beginning with the CY 2019 reporting period/FY 2021 payment determination to streamline reporting through the HAC Reduction Program.

Currently, the CLABSI measure used in the HAC Reduction and Hospital VBP Programs does not include inpatients in cancer wards. Because patients with cancer are especially vulnerable to developing HAIs like CLABSIs,[336] it is important to implement quality reporting for patients with cancer, as we have done in adopting the CLABSI measure in the PCHQR Program. While central lines are a crucial component of cancer treatment, they are also associated with at least 400,000 bloodstream infections in oncology patients every year in the U.S.[337] CLABSIs in patients with cancer may lead to sepsis, require interruptions in chemotherapy, and increase the hospital length of stay.[338] CLABSIs among patients with cancer also incur a high economic burden, costing the U.S. healthcare system over $18 billion annually.[339] Therefore, it is important to address the needs of this high-risk population and adopt the CLABSI-Onc measure to the Hospital IQR Program. The adoption of this measure would also provide more data to compare CLABSI rates between PCHs and non-PCHs.

(b) Overview of Measure

We are proposing to adopt the CLABSI-Onc measure to the Hospital IQR Program beginning with the CY 2026 reporting period/FY 2028 payment determination. The purpose of this measure is to promote CLABSI prevention activities and reduce the incidence of CLABSIs for patients with cancer. Unlike the version of the measure previously in the Hospital IQR Program and that is currently in the HAC Reduction and Hospital VBP Programs, this version we are proposing to adopt is limited to inpatients at acute care hospitals in oncology wards. To

[325] Agency for Healthcare Research and Quality. (2017). Estimating the Additional Hospital Inpatient Cost and Mortality Associated With Selected Hospital-Acquired Conditions. Available at: *https://www.ahrq.gov/hai/pfp/haccost2017-results.html.*

[326] CDC. (2022). Antibiotic Resistance & Patient Safety Portal: Central Line-Associated Bloodstream Infections. Available at: *https://arpsp.cdc.gov/profile/nhsn/clabsi.*

[327] Ibid.

[328] DiBiase, L., Summerlin-Long, S., Stancill, L., Vavalle, E., Teal, L., & Weber, D. (2023). Examining CLABSI rates by central-line type. *Antimicrobial Stewardship & Healthcare Epidemiology, 3*(S2), S48–S49. doi:10.1017/ash.2023.288.

[329] Chovanec, K., Arsene, C., Gomez, C., Brixey, M., Tolles, D., Galliers, J. W., Kopaniasz, R., Bobash, T., & Goodwin, L. (2021). Association of CLABSI With Hospital Length of Stay, Readmission Rates, and Mortality: A Retrospective Review. *Worldviews on evidence-based nursing, 18*(6), 332–338. *https://doi.org/10.1111/wvn.12548.*

[330] Bell, T., & O'Grady, N. P. (2017). Prevention of Central Line-Associated Bloodstream Infections. *Infectious disease clinics of North America,* 31(3), 551–559. *https://doi.org/10.1016/j.idc.2017.05.007.*

[331] CDC. (2011). Central Line-associated Bloodstream Infections: Resources for Patients and Healthcare Providers. Available at: *https://www.cdc.gov/hai/bsi/clabsi-resources.html#print.*

[332] Grigonis, A. M., Dawson, A. M., Burkett, M., Dylag, A., Sears, M., Helber, B., & Snyder, L. K. (2016). Use of a Central Catheter Maintenance Bundle in Long-Term Acute Care Hospitals. *American journal of critical care: an official publication, American Association of Critical-Care Nurses, 25*(2), 165–172. *https://doi.org/10.4037/ajcc2016894.*

[333] Wei, A. E., Markert, R. J., Connelly, C., & Polenakovik, H. (2021). Reduction of central line-associated bloodstream infections in a large acute care hospital in Midwest United States following implementation of a comprehensive central line insertion and maintenance bundle. *Journal of infection prevention, 22*(5), 186–193. *https://doi.org/10.1177/17571774211012471.*

[334] Burke, C., Jakub, K., & Kellar, I. (2021). Adherence to the central line bundle in intensive care: An integrative review. *American journal of infection control, 49*(7), 937–956. *https://doi.org/10.1016/j.ajic.2020.11.014.*

[335] CDC. (2011). Guidelines for the Prevention of Intravascular Catheter-Related Infections. Available at: *https://www.cdc.gov/infectioncontrol/guidelines/BSI/index.html.*

[336] Page, J., Tremblay, M., Nicholas, C., & James, T.A. (2016). Reducing Oncology Unit Central Line-Associated Bloodstream Infections: Initial Results of a Simulation-Based Educational Intervention. *Journal of oncology practice, 12*(1), e83–e87. *https://doi.org/10.1200/JOP.2015.005751.*

[337] Raad, I., & Chaftari, A.M. (2014). Advances in prevention and management of central line-associated bloodstream infections in patients with cancer. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, 59 Suppl 5,* S340–S343. *https://doi.org/10.1093/cid/ciu670.*

[338] Page, J., Tremblay, M., Nicholas, C., & James, T.A. (2016). Reducing Oncology Unit Central Line-Associated Bloodstream Infections: Initial Results of a Simulation-Based Educational Intervention. *Journal of oncology practice, 12*(1), e83–e87. *https://doi.org/10.1200/JOP.2015.005751.*

[339] Raad, I., & Chaftari, A.M. (2014). Advances in prevention and management of central line-associated bloodstream infections in patients with cancer. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, 59 Suppl 5,* S340–S343. *https://doi.org/10.1093/cid/ciu670.*

report this measure, hospitals would need to verify that all locations, including those housing oncology patients, are correctly in NHSN.

Reducing the CLABSI incidence through the adoption of this measure could lead to improved cancer patient outcomes, including reduced morbidity and mortality, less need for antimicrobials, and reduced patient length of stays and medical costs.[340]

(c) Measure Alignment to Strategy

The proposal to adopt the CLABSI-Onc measure supports the CMS National Quality Strategy priority area of ''Safety and Resiliency.'' Specifically, this supports our safety goal to ''achieve zero preventable harm,'' and to expand the collection and use of safety indicator data across programs for key areas to improve tracking and show progress toward reducing harm. The adoption of this measure additionally supports the ''Outcomes and Alignment'' priority area in the CMS National Quality Strategy by collaborating with other federal agencies, namely the CDC, to promote alignment in quality measurement and close the existing reporting gap among vulnerable patients with cancer in inpatient settings.[341] This proposal to adopt CLABSI-Onc not only supports two of the CMS National Quality Strategy priority areas, it also supports the Biden-Harris Administration's Cancer Moonshot program that aims to improve outcomes for patients with cancer.

(d) Pre-Rulemaking Process and Measure Endorsement

(i) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the PRMR process including the voting procedures the PRMR process uses to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List), including the CLABSI-Onc measure (MUC2023–219),[342] [343] and to vote on a recommendation with regard to use of this measure.[344]

The committee reached consensus and recommended including this measure in the Hospital IQR Program with conditions. Fourteen members of the group recommended adopting the measure into the Hospital IQR Program without conditions; four members recommended adoption with conditions; and one committee member voted not to recommend the measure for adoption. Taken together, 94.7 percent of the votes recommended the measure.[345]

Four members of the voting committee recommended the adoption of this measure into the Hospital IQR Program, with the first condition being that CMS consider expanding the reporting period. This would increase the patient volume included in the denominator and increase precision. We have reviewed this recommendation and concluded that expanding the reporting period would result in a critical loss in the ability to observe changes in the SIR over time. Obscuring any observable changes in the SIR would degrade the measure's ability to assess prevention efforts and further drive quality improvement. Therefore, we are proposing this measure for adoption without the modification suggested by four committee members in order to preserve the measure's ability to observe changes in the SIR more quickly.

The second condition the committee recommended for the Hospital IQR Program was that the measure should evaluate data by oncology unit type, such as hematology-oncology versus solid organ.[346] We acknowledge this condition and may consider it for future rulemaking. We are proposing to adopt the CLABSI-Onc measure in the Hospital IQR Program having taken into consideration the conditions raised by the PRMR Hospital Recommendation Committee.

The measure received strong support from the committee as it addresses an important patient safety concern. During the committee's discussion, some expressed concern about the burden of manual abstraction. Others asked about the measure's validity, and whether the measure should include risk adjustments when HAIs are an issue across the board.

(ii) Measure Endorsement

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees use to evaluate measures and whether they meet endorsement criteria. The CLABSI measure was most recently submitted to the CBE for endorsement review in the Spring 2019 cycle (CBE #0139) and was endorsed on October 23, 2019.[347] In the submission of the CLABSI-Onc measure to the 2023 MUC list, the CDC provided additional oncology-only reliability testing based on existing data submitted to the CDC's NHSN. Because the CLABSI-Onc measure has the same specifications as the CLABSI measure, with the only difference being that it is stratified for oncology locations, additional endorsement of CLABSI-Onc is not necessary. The calculations pertinent to those locations are inherently part of the endorsement performed for the CLABSI measure, and the measure (*i.e.,* numerator/denominator) is endorsed across all inpatient hospital settings, including oncology locations. The calculation of the SIR includes and accounts for the location of the patient within the facility. The CDC will incorporate information on the stratification by oncology patients during the regularly scheduled measure maintenance re-endorsement process.

(e) Measure Specifications

For this measure, the NHSN calculates the quarterly risk-adjusted SIR of CLABSIs among inpatients at acute care hospitals who are in oncology wards.[348] The CDC then calculates the SIR using all four quarters of data from the reporting period year, which CMS uses for performance calculation and public reporting purposes. The CDC defines an oncology ward as an area for

[340] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[341] CMS National Quality Strategy. (2023). Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[342] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[343] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[344] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/PRMR.*

[345] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Final MUC Recommendation Report. Available at: *https://p4qm.org/PRMR.*

[346] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/PRMR.*

[347] Battelle—Partnership for Quality Measurement. NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure. Available at: *https://p4qm.org/measures/0139.*

[348] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

the evaluation and treatment of patients with cancer. For more details, we refer readers to the CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations document.[349]

The numerator is the number of annually observed CLABSIs among acute care hospital inpatients in oncology wards. The denominator is the number of annually predicted CLABSIs among acute care hospital inpatients in oncology wards. By dividing the number of observed CLABSIs by the number of predicted CLABSIs, the SIR compares the actual number of cases to the expected number of cases. However, this does not preclude SIRs from being ranked. The SIR is calculated when there is at least one predicted CLABSI, to achieve a minimum level of precision.[350]

The measure requires a facility to have at least one predicted CLABSI before calculating the SIR because the precision of a facility's CLABSI rate can vary, especially in low volume hospitals. For this reason, the NHSN calculates the SIR instead of reporting the CLABSI rate directly. A facility's SIR is not meant to be compared directly to that of another facility. Rather, the primary role of the SIR is to compare a facility's CLABSI rate to the national rate after adjusting for facility- and patient-level risk factors.[351]

The numerator and denominator exclude the following devices because they are not considered central lines: arterial catheters unless in the pulmonary artery, aorta or umbilical artery, arteriovenous fistula, arteriovenous graft, atrial catheters (also known as transthoracic intra-cardiac catheters, those catheters inserted directly into the right or left atrium via the heart wall), extracorporeal membrane oxygenation (ECMO), hemodialysis reliable outflow (HERO) dialysis catheter, intra-aortic balloon pump (IABP) devices, peripheral IV or midlines, or ventricular assist devices (VAD). Additionally, CLABSI events reported to the NHSN as mucosal barrier injury laboratory-confirmed bloodstream infections (MBI–LCBIs) are excluded.[352]

The SIR also adjusts for various facility and patient-level factors that contribute to HAI risk within each facility. For more information on the risk adjustment methodology please reference the CDC website at: *https://www.cdc.gov/nhsn/2022rebaseline/index.html.*

(f) Data Submission and Reporting

We are proposing to collect data for the CLABSI-Onc measure via the NHSN, consistent with the current approach for HAI reporting for the HAC Reduction and Hospital VBP Programs. The NHSN is a secure, internet-based surveillance system maintained and managed by the CDC and provided free of charge to providers. To report to the NHSN, hospitals must first agree to the NHSN Agreement to Participate and Consent form, which specifies how NHSN data will be used, including fulfilling CMS's quality measurement reporting requirements for NHSN data.[353]

Starting in 2011, facilities operating under the Hospital IQR Program began reporting CLABSIs in all adult, pediatric, and neonatal intensive care locations followed by reporting all adult and pediatric medical, surgical, and medical/surgical wards in 2015 using NHSN. According to a 2022 CDC report, 3,728 hospitals are reporting CLABSI data to NHSN; of these, 488 hospitals reported data from at least one oncology location.[354] We anticipate that because most of the hospitals which would begin to report the CLABSI-Onc measure for the Hospital IQR Program are already reporting via NHSN for other measures, they have already set up an account. Hospitals currently reporting CLABSI must verify that locations housing oncology patients are correctly mapped as an oncology location based on NHSN's location mapping guidance for accurate event location attribution.

Hospitals would report their data for the CLABSI-Onc measure on a quarterly basis for the purposes of Hospital IQR Program requirements. Presently, hospitals report CLABSI data to the NHSN monthly and the SIR is calculated on a quarterly basis. Under the data submission and reporting process, hospitals would collect the numerator and denominator for the CLABSI–ONC measure each month and submit the data to the NHSN. The data from all 12 months would be calculated into quarterly reporting periods which would then be used to determine the SIR for CMS performance calculation and public reporting purposes. We refer readers to the NHSN website for further information about NHSN reporting requirements. We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59141) for information on data submission and reporting requirements for our most recent updates to data submission and reporting requirements for measures submitted via the CDC NHSN.

We invite public comment on our proposal to adopt the CLABSI-Onc measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

c. Proposal To Adopt the Hospital Harm—Falls With Injury eCQM Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

(1) Background

Patient falls are among the most common hospital harms reported and can increase length of stay and patient costs.[355] [356] [357] It has been estimated that there are 700,000–1,000,000 inpatient falls in the U.S. annually, with more than one-third resulting in injury and up to 11,000 resulting in patient death.[358] [359] Protocols and prevention measures to reduce patient falls with injury include using fall risk assessment tools to gauge individual patient risk, implementing fall prevention protocols directed at individual patient risk

[349] CDC. (2023). CDC Locations and Descriptions and Instructions for Mapping Patient Care Locations. Available at: *https://www.cdc.gov/nhsn/pdfs/pscmanual/15locationsdescriptions_current.pdf.*

[350] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[351] CDC. (2022). NHSN SIR Guide. Available at: *https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf.*

[352] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[353] CDC. (2023). FAQs About NHSN Agreement to Participate and Consent. Available at: *https://www.cdc.gov/nhsn/about-nhsn/faq-agreement-to-participate.html.*

[354] CDC. (2022). National and State Healthcare-associated Infections Progress Report. Available at: *https://www.cdc.gov/hai/data/portal/progress-report.html.*

[355] Bysshe, T., Gao, Y., Heaney-Huls, K., et al. (2017). Final Report Estimating the Additional Hospital Inpatient Cost and Mortality Associated with Selected Hospital Acquired Conditions.

[356] Morello, R.T., Barker, A.L., Watts, J.J., Haines, T., Zavarsek, S.S., Hill, K.D., Brand, C., Sherrington, C., Wolfe, R., Bohensky, M.A., & Stoelwinder, J.U. (2015). The Extra Resource Burden of In-hospital Falls: a Cost of Falls Study. *The Medical Journal of Australia, 203*(9), 367. *https://doi.org/10.5694/mja15.00296.*

[357] Dykes, P.C., Curtin-Bowen, M., Lipsitz, S., Franz, C., Adelman, J., Adkison, L., Bogaisky, M., Carroll, D., Carter, E., Herlihy, L., Lindros, M.E., Ryan, V., Scanlan, M., Walsh, M.A., Wien, M., & Bates, D.W. (2023). Cost of Inpatient Falls and Cost-Benefit Analysis of Implementation of an Evidence-Based Fall Prevention Program. *JAMA Health Forum, 4*(1), e225125. *https://doi.org/10.1001/jamahealthforum.2022.5125.*

[358] AHRQ. (2019). Patient Safety Primer: Falls. Retrieved July 24, 2019, from AHRQ PSNet website: *https://psnet.ahrq.gov/primers/primer/40/*Falls.

[359] Currie, L. (2008). Fall and Injury Prevention. In E. Hughes RG (Ed.), Patient Safety and Quality: An Evidence-Based Handbook for Nurses (pp. 195–250). Rockville: Agency for Healthcare Research and Quality.

factors, and implementing environmental rounds to assess and correct environmental fall hazards.[360] There is wide variation in fall rates between hospitals which suggests that this is an area where quality measurement and further improvement is still needed.[361] [362] [363] [364]

Currently there are no electronic clinical quality measures (eCQMs) that focus specifically on acute care inpatient falls with major or moderate injury in any of the hospital quality reporting or value-based purchasing programs. The Patient Safety Indicator (PSI) 90 composite measure,[365] which is currently included in the HAC Reduction Program, does include a fall related component, (PSI 08): In Hospital Fall-Associated Fracture Rate; however, it is a claims-based measure that uses a two-year performance period, it is focused on the Medicare Fee For Service (FFS) population, and the numerator is limited to fractures and does not include other fall-associated major and moderate injuries. In the FY 2022 IPPS/LTCH PPS final rule, we highlighted our commitment to developing new digital quality measures that assess various aspects of patient safety in the inpatient setting (87 FR 49181 through 49190). As discussed later in this section of the preamble, the Hospital Harm—Falls with Injury eCQM provides the opportunity to assess the rate of falls that result in a wider range of injuries, in a much larger patient population, and using more timely information from patients' electronic medical records instead of administrative claims data.

(2) Overview of Measure

The Hospital Harm—Falls with Injury measure is a risk-adjusted outcome eCQM. The denominator is inpatient hospitalizations for patients aged 18 and older with a length of stay less than or equal to 120 days that ends during the measurement period. The numerator is inpatient hospitalizations where the patient has a fall that results in moderate injury (such as lacerations, open wounds, dislocations, sprains, and strains) or major injury (such as fractures, closed head injuries, internal bleeding). The diagnosis of a fall and of a moderate or major injury that was present on admission would be excluded from the measure.

The baseline risk-adjustment model accounts for age and several risk factors present on admission (weight loss or malnutrition, delirium, dementia, and other neurological disorders).[366] The risk-adjustment model has been developed to ensure that hospitals that care for sicker and more complex patients are evaluated fairly.[367] We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah*) for more details on the measure specifications and risk methodology.

(3) Measure Alignment to Strategy

This measure aligns with several goals under the CMS National Quality Strategy in addition to supporting our re-commitment to better patient and healthcare worker safety.[368] The COVID–19 public health emergency (PHE) put significant strain on hospitals and health systems which negatively impacted patient safety in routine care delivery, highlighting the need to address gaps in safety. Proposing the Hospital Harm—Falls with Injury measure is one of several initial actions we are taking in response to the President's Council of Advisors on Science and Technology (PCAST) call to action to renew ''our nation's commitment to improving patient safety.'' [369] By establishing additional safety indicators, such as this measure, we are building a stronger, more resilient U.S. healthcare system. We refer readers to section IX.B.1. for more details on other efforts toward better patient and healthcare workers safety practices and the proposal to adopt the Patient Safety Structural measure into the Hospital IQR Program and the PCHQR Program.

This measure aligns with the ''Safety and Resiliency'' goal of our CMS National Quality Strategy to achieve zero preventable harm, the ''Equity and Engagement'' goal to ensure that all individuals have the information needed to make the best choices and complements the HHS National Action Alliance to Advance Patient Safety. By providing hospitals with the opportunity to assess the rate of falls with injury in a much larger patient population (all-payer) compared to current measures such as PSI 08 (limited to Medicare FFS), this measure expands the available safety indicator data within CMS programs and promotes equitable care for all. This measure additionally supports the ''Outcomes and Alignment'' goals to improve quality and health outcomes by providing hospitals a mechanism to track falls with injury event rates and improve falls intervention efforts over time, a key patient safety metric across the care journey. Third, this measure supports CMS' Interoperability goal to improve quality measure efficiency by transitioning to digital measures in CMS quality reporting programs. As an eCQM, this measure increases the digital measure footprint and can also serve as a potential replacement for the claims-based PSI 08 measure (reported within the PSI 90 composite) in the future.

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of the preamble of this is proposed rule for details on the PRMR process including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List), including the Hospital Harm—Falls with Injury measure (MUC2023–048), and to vote on a recommendation with regard to use of this measure.[370] [371]

[360] Montero-Odasso, M., Van der Velde, N., Martin, F.C., et al. (2022). World Guidelines for Falls Prevention and Management for Older Adults: A Global Initiative. *Age and Ageing,* 51(9), 1–36.

[361] Staggs, V.S., Mion, L.C., & Shorr, R.I. (2015). Consistent Differences in Medical Unit Fall Rates: Implications for Research and Practice. *Journal of the American Geriatrics Society,* 63(5), 983–987. *https://doi.org/10.1111/jgs.13387.*

[362] Registered Nurses' Association of Ontario. (2017). Preventing Falls and Reducing Injury from Falls (4th ed.). Toronto, ON: Registered Nurses' Association of Ontario.

[363] National Institute of Health and Care Excellence. (2013). Falls in Older People: Assessing Risk and Prevention.

[364] ACS National Surgical Quality Improvement Program (NSQIP)/American Geriatrics Society (AGS). (2016). Optimal Perioperative Management of the Geriatric Patient: Best Practices Guideline from ACS NSQIP/AGS. *https://www.facs.org/media/y5efmgox/acs-nsqip-geriatric-2016-guidelines.pdf.*

[365] PSI 90 Technical Specification can be found here: *https://qualitynet.cms.gov/inpatient/measures/psi/resources.*

[366] Battelle—Partnership for Quality Measurement. Hospital Harm—Falls with Injury. Available at: *https://p4qm.org/measures/4120e.*

[367] Ibid.

[368] CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[369] President's Council of Advisors on Science and Technology. (2023). Report to the President: A Transformational Effort on Patient Safety. *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.*

[370] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[371] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

The committee reached consensus and recommended including this measure in the Hospital IQR Program with conditions. Twelve members of the group voted to adopt the measure into the Hospital IQR Program without conditions; six members voted to adopt with conditions; one committee member voted not to recommend the measure for adoption. Taken together, 94.7 percent of the votes were recommended or recommended with conditions. The six members who voted to adopt with conditions, specified the condition as monitoring unintended for consequences, such as use of patient restraints. We agree that the potential for unintended consequences exists and note that we consistently monitor all of the measures in the Hospital IQR Program for unintended consequences. Furthermore, we note that under our previously finalized measure removal Factor 6, collection or public reporting of a measure leads to negative unintended consequences other than patient harm, if we were to identify unintended consequences related to this measure we would consider it for removal. Furthermore, we note that various programs have been instituted that reduce hospital falls without decreasing mobility (such as the Hospital Elder Life Program) [372] and that the benefits of promoting mobility outweigh any increase in fall risk.[373]

(b) Measure Endorsement

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees uses to evaluate measures and whether they meet endorsement criteria. The E&M Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health Committee [374] convened in the Fall 2023 cycle to review the Hospital Harm—Falls with Injury measure (CBE #4120e) submitted to the CBE for endorsement. The E&M Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health Committee ultimately voted to endorse the measure on January 29, 2024.[375]

(5) Measure Specifications

This ratio measure is reported as the number of inpatient hospitalizations with falls with moderate or major injury per 1,000 patient days. The measure is calculated using the following: (Total number of encounters with falls with moderate or major injury/total number of eligible hospital days) × 1,000. To calculate the numerator (that is, the total number of encounters with falls with moderate or major injury): (1) identify the initial population (inpatient hospitalizations for patients aged 18 and older with a length of stay less than or equal to 120 days that ends during the measurement period), (2) remove exclusions (patients who had a fall diagnosis present at the time the order for inpatient admission occurs), and (3) determine if the patient meets numerator criteria (patient has both a fall diagnosis and major or moderate injury diagnosis not present on admission). Hospital days are measured in 24-hour periods starting from the time of arrival at the hospital (including time in the emergency department and or observation). The number of hospital days is rounded down to whole numbers; any fractional periods are dropped. All data elements necessary to calculate the numerator and denominator are defined within value sets available in the Value Set Authority Center (VSAC).[376]

The measure was tested in 12 hospital test sites with two different EHR vendors (Epic and Allscripts) with varying bed size, geographic location, and teaching status. Risk-adjusted rates showed substantial variation in performance scores across the 12 test hospitals indicating ample room for quality improvement.[377] Test results using one year of data indicated strong measure reliability and validity (including agreement between data exported from the EHR and data in the patient chart).[378] As PSI 08 uses a two-year performance period, this eCQM would allow hospitals to receive more timely information about measure performance.

We recognize there may be stakeholder concern regarding measure duplication with PSI 08 (a component of PSI 90 that is currently measured and publicly reported in the HAC Reduction Program). However, as described earlier, the Hospital Harm—Falls with Injury eCQM provides the opportunity to assess the rate of falls with a wider range of injuries in a larger population compared to PSI 08. We envision the potential future use of patient safety eCQMs not only in the Hospital IQR Program, but also pay-for-performance programs such as the HAC Reduction Program, including as a potential replacement for the claims-based PSI 90 measure. However, until that time we intend to retain PSI 08 (within the PSI 90 composite) in the HAC Reduction Program as well as include the Hospital Harm—Falls with Injury eCQM in the Hospital IQR Program.

(6) Data Submission and Reporting

This eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' certified electronic health record technology (CEHRT) using patient-level data and then submitted by hospitals to CMS. As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing demonstrated that all critical data elements were reliably and consistently captured in hospital EHRs and measure implementation is feasible.

We are proposing the adoption of the Hospital Harm—Falls with Injury eCQM as part of the eCQM measure set beginning with the CY 2026 reporting period/FY 2028 payment determination. The eCQM measure set is the measure set from which hospitals can self-select measures to report to meet the eCQM reporting requirement. We refer readers to section IX.C.9.c. of this proposed rule for a discussion of our previously finalized eCQM reporting and submission requirements, as well as proposed modifications for these requirements. Additionally, we refer readers to section IX.F.6.a.(2). of the preamble of this proposed rule for a discussion of a similar proposal to adopt

[372] Hshieh, T.T., Yue, J., Oh, E., Puelle, M., Dowal, S., Travison, T., & Inouye, S.K. (2015). Effectiveness of multicomponent nonpharmacological delirium interventions: a meta-analysis. JAMA internal medicine, 175(4), 512–520. *https://doi.org/10.1001/jamainternmed.2014.7779.*

[373] Montero-Odasso, M., van der Velde, N., Martin, F.C., Petrovic, M., Tan, M.P., Ryg, J., Aguilar-Navarro, S., Alexander, N.B., Becker, C., Blain, H., Bourke, R., Cameron, I.D., Camicioli, R., Clemson, L., Close, J., Delbaere, K., Duan, L., Duque, G., Dyer, S.M., . . . Rixt Zijlstra, G.A. (2022). World guidelines for falls prevention and management for older adults: a global initiative. Age and Ageing, 51(9), 1–36.

[374] Battelle—Partnership for Quality Measurement. Hospital Harm—Fall Injury Measure Specifications. Available at: *https://p4qm.org/measures/4120e.*

[375] Battelle—Partnership for Quality Measurement. 2023 Management of Acute and Chronic Events Meeting Summary. *https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Acute-Chronic-Events-Fall2023-Endorsement-Meeting-Summary.pdf.*

[376] To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at *https://vsac.nlm.nih.gov/.*

[377] Battelle—Partnership for Quality Measurement. Hospital Harm—Falls with Injury. Available at: *https://p4qm.org/measures/4120e.*

[378] Ibid.

this measure in the Medicare Promoting Interoperability Program.

We invite public comment on our proposal to adopt the Hospital Harm—Falls with Injury eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination.

d. Proposal To Adopt the Hospital Harm—Postoperative Respiratory Failure eCQM Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

(1) Background

Postoperative respiratory failure is defined as unplanned intubation or prolonged mechanical ventilation (MV) after an operation.[379] It is considered to be the most serious of the postoperative respiratory complications because it represents the ''end stage'' of several types of pulmonary complications (for example, pneumonia, aspiration, pulmonary edema, and acute respiratory distress syndrome) and non-pulmonary problems (for example, sepsis, oversedation, seizures, stroke, heart failure, pulmonary embolism, and fluid overload), and it often results in negative outcomes, including prolonged morbidity, longer hospital stays, increased readmissions, higher costs, or death.[380] [381] [382] Postoperative respiratory failure is potentially preventable with optimal care, such as carefully managing intraoperative ventilator use and fluids, reducing surgical duration, using regional anesthesia, and preventing wound infection and pain.[383] [384] [385] Published data suggest room for improvement; a Nationwide Inpatient Sample (NIS) database study of over 500,000 hospitalizations involving a brain tumor between 2002 and 2010 found the incidence of postoperative respiratory failure varied by hospital characteristics, with higher reported rates of postoperative respiratory failure in nonteaching hospitals than teaching hospitals, and incidence increased with hospital bed size.[386]

Currently there are no eCQMs that focus specifically on postoperative respiratory failure in the inpatient setting in any of the hospital quality reporting or value-based purchasing programs. The PSI 90 composite measure,[387] which is currently included in the HAC Reduction Program, does include a postoperative respiratory failure related component, (PSI 11): Postoperative Respiratory Failure Rate; however, it is a claims-based measure that uses a two-year performance period, it is focused on the Medicare FFS population, and is dependent upon ICD–10–CM codes. In the FY 2022 IPPS/LTCH PPS final rule, we highlighted our commitment to developing new digital quality measures that assess various aspects of patient safety in the inpatient setting (87 FR 49181 through 49190). The Hospital Harm—Postoperative Respiratory Failure eCQM provides the opportunity to assess the rate of postoperative respiratory failure in a much larger patient population and use more timely information from patients' electronic medical records instead of administrative claims data.

(2) Overview of Measure

The Hospital Harm—Postoperative Respiratory Failure measure is a risk-adjusted outcome eCQM. The denominator is elective inpatient hospitalizations that end during the measurement period for patients 18 years old and older without an obstetrical condition and at least one surgical procedure was performed within the first three days of the encounter.[388] The numerator is elective inpatient hospitalizations for patients with postoperative respiratory failure: For more detail on how postoperative respiratory failure is determined we refer readers to the measure specifications at the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah*).

The baseline risk-adjustment model accounts for ten comorbidities present on admission (weight loss, deficiency anemias, heart failure, diabetes with chronic complications, moderate to severe liver disease, peripheral vascular disease, pulmonary circulation disease, valvular disease, ASA categories 3 through 5) and lab values for oxygen (partial pressure), leukocytes, albumin, BUN, bilirubin, and pH of arterial blood.[389] The risk-adjustment ensures that hospitals that care for sicker and more complex patients are evaluated fairly.[390] We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah*) for more details on the measure specifications and risk-adjustment methodology.

(3) Measure Alignment to Strategy

This measure aligns with several goals under the CMS National Quality Strategy in addition to supporting our re-commitment to better patient and healthcare worker safety.[391] The COVID–19 public health emergency (PHE) highlighted the need to address gaps in safety by putting significant strain on hospitals and health systems which, in turn, negatively impacted patient safety. Proposing the Hospital Harm—Postoperative Respiratory Failure measure is one of several initial actions we are taking in response to the President's Council of Advisors on Science and Technology (PCAST), call to action to renew ''our nation's commitment to improving patient safety.'' [392] By establishing additional safety indicators, such as this measure, we are building a stronger, more resilient U.S. healthcare system. We refer readers to section IX.B.1. for more details on other efforts toward better patient and healthcare workers safety practices and the proposal to adopt the Patient Safety Structural measure into

[379] Stocking, J.C., Utter, G.H., Drake, C., Aldrich, J.M., Ong, M.K., Amin, A., Marmor, R.A., Godat, L., Cannesson, M., Gropper, M.A., & Romano, P.S. (2020). Postoperative Respiratory Failure: An Update on the Validity of the Agency for Healthcare Research and Quality Patient Safety Indicator 11 in an Era of Clinical Documentation Improvement Programs. *American Journal of Surgery, 220*(1), 222–228. *https://doi.org/10.1016/j.amjsurg.2019.11.019.*

[380] Sabate S., Mazo V., Canet J. (2014). Predicting Postoperative Pulmonary Complications: Implications for Outcomes and Costs. *Case Reports in Anesthesiology.* 27(2), 201–209.

[381] Rosen, A.K., Loveland, S., Shin, M., Shwartz, M., Hanchate, A., Chen, Q., Kaafarani, H.M., & Borzecki, A. (2013). Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical Care,* 51(1), 37–44.

[382] Lawson E.H., Hall B.L., Louie R., et al. (2013). Association Between Occurrence of a Postoperative Complication and Readmission: Implications for Quality Improvement and Cost Savings. *Annals of Surgery,* 258(1),10–18.

[383] Stocking, J.C., Drake, C., Aldrich, J.M., Ong, M.K., Amin, A., Marmor, R.A., Godat, L., Cannesson, M., Gropper, M.A., Romano, P.S., Sandrock, C., Bime, C., Abraham, I., & Utter, G.H. (2022). Outcomes and Risk Factors for Delayed-onset Postoperative Respiratory Failure: A Multicenter Case-control Study by the University of California Critical Care Research Collaborative (UC[3]RC). *BMC Anesthesiology,* 22(1), 146.

[384] Encinosa, W.E., & Hellinger, F.J. (2008). The Impact of Medical Errors on Ninety-day Costs and Outcomes: An Examination of Surgical Patients. *Health Services Research,* 43(6), 2067–2085.

[385] Zrelak, P.A., Utter, G.H., Sadeghi, B., Cuny, J., Baron, R., & Romano, P.S. (2012). Using the Agency for Healthcare Research and Quality patient safety indicators for targeting nursing quality improvement. *Journal of Nursing Care Quality,* 27(2), 99–108.

[386] Rahman, M., Neal, D., Fargen, K.M., & Hoh, B.L. (2013). Establishing Standard Performance Measures for Adult Brain Tumor Patients: A Nationwide Inpatient Sample Database Study. *Neuro-oncology,* 15(11), 1580–1588.

[387] PSI 90 Technical Specification can be found here: *https://qualitynet.cms.gov/inpatient/measures/psi/resources.*

[389] Battelle—Partnership for Quality Measurement. Hospital Harm—Postoperative Respiratory Failure. Available at: *https://p4qm.org/measures/4130e.*

[390] Ibid.

[391] CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[392] President's Council of Advisors on Science and Technology. (2023). Report to the President: A Transformational Effort on Patient Safety. *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.*

the Hospital IQR Program and the PCHQR Program.

In alignment with the CMS National Quality Strategy [393] this measure supports the ''Safety and Resiliency'' goal to achieve zero preventable harm, the ''Equity and Engagement'' goal to ensure that all individuals have the information needed to make the best choices and complements the HHS National Action Alliance to Advance Patient Safety. By providing hospitals the opportunity to assess postoperative respiratory failure rates in a much larger patient population (all-payer) compared to current measures such as PSI 11 (limited to Medicare FFS), this measure expands the available safety indicator data within CMS programs and promotes equitable care for all. Second, this measure supports the ''Outcomes and Alignment'' goals to improve quality and health outcomes by providing hospitals a mechanism to track their postoperative respiratory failure incidents and improve harm reduction efforts over time, a key patient safety metric across the care journey. Third, this measure supports CMS' Interoperability goal to improve quality measure efficiency by transitioning to digital measures in CMS quality reporting programs. As an eCQM, this measure increases the digital measure footprint and can also serve as a potential replacement for the claims-based PSI 11 measure (reported within the PSI–90 composite) in the future.

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the PRMR process including the voting used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List),[394] [395] including the Hospital Harm—Postoperative Respiratory Failure measure (MUC2023–050), and to vote on a recommendation for rulemaking for the Hospital IQR Program.

The committee reached consensus and recommended including this measure in the Hospital IQR Program with conditions. Twelve members of the group voted to adopt the measure into the Hospital IQR Program without conditions; five members voted to adopt with conditions; two committee members voted not to recommend the measure for adoption. Taken together, 89.5 percent of the votes were between recommend and recommend with conditions. The five members who voted to adopt with conditions specified the condition as monitoring unintended consequences, such as avoidance of life-saving procedures with higher risk for respiratory failure. We agree that the potential for unintended consequences exists and note that we consistently monitor all of the measures in the Hospital IQR Program for unintended consequences. Furthermore, we note that under our previously finalized measure removal Factor 6, collection or public reporting of a measure leads to negative unintended consequences other than patient harm, if we were to identify unintended consequences related to this measure, we would consider it for removal. Furthermore, the measure logic allows for the use of mechanical ventilation or intubation or extubation documentation outside of a procedural area to trigger a postoperative respiratory event, thus expanding opportunities for electronic capture of information and accommodating varying clinical documentation workflows.

(b) Measure Endorsement

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees uses to evaluate measures and whether they meet endorsement criteria. The E&M Management of Acute and Chronic Events Committee convened in the Fall 2023 cycle to review the Hospital Harm—Postoperative Respiratory Failure measure (CBE #4130e) submitted to the CBE for endorsement.[396] The E&M Management of Acute and Chronic Events Committee ultimately voted to endorse the measure on January 29, 2024.[397]

(5) Measure Calculation

Postoperative respiratory failure is evaluated using MV documentation, intubation or extubation documentation to determine if an unplanned initiation of MV occurred or if MV was continued without interruption after a procedure.

The following calculation is applied to report the overall performance rate: [Number of encounters in numerator/(Number of encounters in denominator—Number of encounters in denominator exclusions)] × 1,000. All data elements necessary to calculate the numerator and denominator are defined within value sets available in the VSAC.[398]

The measure was tested in 12 hospitals (test sites) with two different EHR vendors (Epic and Cerner) with varying bed size, geographic location, and teaching status. Risk-adjusted rates showed substantial variation in performance scores across the 12 test hospitals.[399] Test results indicated high measure reliability and validity (including agreement between data exported from the EHR and data in the patient chart).[400]

(6) Data Submission and Reporting

This eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using patient-level data and then submitted by hospitals to CMS. As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing demonstrated that all critical data elements were reliably and consistently captured in patient EHRs and measure implementation is feasible.

We are proposing the adoption of the Hospital Harm—Postoperative Respiratory Failure eCQM as part of the eCQM measure set beginning with the CY 2026 reporting period/FY 2028 payment determination. The eCQM

[393] CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[394] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[395] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[396] Battelle—Partnership for Quality Measurement. Hospital Harm—Postoperative Respiratory Failure. Available at: *https://p4qm.org/measures/4130e.*

[397] Battelle—Partnership for Quality Measurement. Fall 2023 Management of Acute and Chronic Events Meeting Summary. Available at: *https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Acute-Chronic-Events-Fall2023-Endorsement-Meeting-Summary.pdf.*

[398] To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at*https://vsac.nlm.nih.gov/.*

[399] Battelle—Partnership for Quality Measurement. Hospital Harm—Postoperative Respiratory Failure. Available at: *https://p4qm.org/measures/4130e.*

[400] Ibid.

measure set is the measure set from which hospitals can self-select measures to report to meet the eCQM reporting requirement. We refer readers to section IX.C.9.c. of this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies, as well as proposed modifications for these requirements. Additionally, we refer readers to section IX.F.6.a.(2). of the preamble of this proposed rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program.

We invite public comment on our proposal to adopt the Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination.

e. Proposal To Adopt the Thirty-Day Risk-Standardized Death Rate Among Surgical Inpatients With Complications (Failure-To-Rescue) Measure Beginning With the FY 2027 Payment Determination

(1) Background

Failure-to-rescue is defined as the probability of death given a postoperative complication.[401] [402] [403] Hospitals can implement evidence-supported interventions to improve timely identification of clinical deterioration and treatment of potentially preventable complications, including improved nurse staffing, simulation training, standardized communication tools, electronic monitoring and/or warning systems, and rapid response systems.[404] [405] [406] [407] [408] [409] Studies also show that other processes of care can influence failure-to-rescue rates, including a hospital's aggressiveness of care (defined as the level of resources or inpatient spending), with hospitals that treat patients more aggressively (such as providing more inpatient days or ICU days in the last 2 years of life) having lower surgical mortality and failure-to-rescue rates than otherwise similar hospitals that treat patients less aggressively.[410] [411] Hospitals and healthcare providers benefit from knowing not only their institution's mortality rate, but also their institution's ability to rescue patients after an adverse occurrence. Using a failure-to-rescue measure is especially important if hospital resources needed for preventing complications are different from those needed for rescue.

This Failure-to-Rescue measure was designed to improve upon the CMS Patient Safety Indicator 04 Death Rate Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure in the Hospital IQR Program. We refer readers to section IX.C.6.a. for our proposal to remove the CMS PSI 04 measure contingent upon the adoption of the Failure-to-Rescue measure. Both the Failure-to-Rescue measure and the CMS PSI 04 measure focus on hospitals' ability to rescue patients who experience clinically significant complications after inpatient operations, so that these complications do not result in death. Both measures are sensitive to factors such as appropriate nurse staffing and nursing skill-mix, which enable hospitals to identify complications earlier and intervene effectively to prevent death.

The proposed Failure-to-Rescue measure directly addresses stakeholder concerns about the CMS PSI 04 measure, including:

- Complications sometimes develop before the index operation in CMS PSI 04, even before transferring to the index hospital. For example, the operation is part of an effort to ''rescue'' the patient.
- The heterogeneous cohort includes patients with very high-risk surgery (for example, trauma surgery, burn surgery, organ transplants, intracranial hemorrhage) and very low-risk surgery (for example, eye, ear, urolithiasis).
- Mean length of stay and prevalence of early discharge to post-acute facilities vary across hospitals, causing bias in comparing performance.
- CMS PSI 04 may slightly disadvantage teaching hospitals, even after risk-adjustment, due to residual confounding from unmeasured case-mix differences.

The proposed Failure-to-Rescue measure has four major differences compared to CMS PSI 04:

1. Captures all deaths of denominator-eligible patients within 30 days of the first qualifying operating room procedure, regardless of site.
2. Limits the denominator to patients in general surgical, vascular, and orthopedic Medicare Severity Diagnosis Related Groups (MS–DRGs).
3. Excludes patients whose relevant complications preceded (rather than followed) their first inpatient operating room procedure, while broadening the definition of denominator-triggering complications to include other complications that may predispose to death (for example, pyelonephritis, osteomyelitis, acute myocardial infarction, stroke, acute renal failure, heart failure/volume overload).
4. Measure cohort includes Medicare Advantage patients.

We are proposing to adopt the Failure-to-Rescue measure beginning with the performance period of July 1, 2023–June 30, 2025 affecting the FY 2027 payment determination.

(2) Overview of Measure

The Failure-to-Rescue measure is a risk-standardized measure of death after hospital-acquired complication. The measure denominator includes patients 18 years old and older admitted for certain procedures in the General Surgery, Orthopedic, or Cardiovascular Medicare Severity Diagnosis Related Groups (MS–DRGs) who were enrolled in the Medicare program and had a documented complication that was not present on admission. The measure numerator includes patients who died within 30 days from the date of their first ''operating room'' procedure, regardless of site of death.

[401] Silber J.H., Williams S.V., Krakauer H., Schwartz J.S., Hospital and patient characteristics associated with death after surgery. A study of adverse occurrence and failure to rescue. Med. Care. 1992 Jul.;30(7):615–29. doi: 10.1097/00005650–199207000–00004.

[402] Needleman J., Buerhaus P., Mattke S., Stewart M., Zelevinsky K., Nurse-staffing levels and the quality of care in hospitals. N. Engl. J. Med. 2002 May 30;346(22):1715–22. doi: 10.1056/NEJMsa012247.

[403] Portuondo J.I., Shah S.R., Singh H., Massarweh N.N., Failure to Rescue as a Surgical Quality Indicator: Current Concepts and Future Directions for Improving Surgical Outcomes. Anesthesiology. 2019 Aug.;131(2):426–437. doi: 10.1097/ALN.0000000000002602.

[404] Silber, J.H., Rosenbaum, P.R., Ross, R. (1995). Comparing the Contributions of Groups of Predictors: Which Outcomes Vary with Hospital Rather than Patient Characteristics? *Journal of the American Statistical Association, 90*(429), 7–18. *https://doi.org/10.2307/2291124.*

[405] Liao, L.M., Sun, X.Y., Yu, H., & Li, J.W. (2016). The Association of Nurse Educational Preparation and Patient Outcomes: Systematic Review and Meta-Analysis. *Nurse Education Today, 42,* 9–16. *https://doi.org/10.1016/j.nedt.2016.03.029.*

[406] Burke, J.R., Downey, C., & Almoudaris, A.M. (2022). Failure to Rescue Deteriorating Patients: A Systematic Review of Root Causes and Improvement Strategies. *Journal of Patient Safety, 18*(1), e140–e155. *https://doi.org/10.1097/PTS.0000000000000720.*

[407] Hall K.K., Lim A., Gale B. (2020). Failure To Rescue. In: Hall, K.K., Shoemaker-Hunt, S., Hoffman, et al. *Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices.* Agency for Healthcare Research and Quality (US).

[408] Hall K.K., Lim A., Gale B. (2020). The Use of Rapid Response Teams to Reduce Failure to Rescue Events: A Systematic Review. *Journal of Patient Safety.*16(3S Suppl 1):S3–S7.

[409] Johnston, M.J., Arora, S., King, D., Bouras, G., Almoudaris, A.M., Davis, R., & Darzi, A. (2015). A Systematic Review to Identify the Factors that Affect Failure to Rescue and Escalation of Care in Surgery. *Surgery, 157*(4), 752–763. *https://doi.org/10.1016/j.surg.2014.10.017.*

[410] Kaestner, R., & Silber, J.H. (2010). Evidence on the Efficacy of Inpatient Spending on Medicare Patients. *The Milbank Quarterly, 88*(4), 560–594.

[411] Silber, J.H., Kaestner, R., Even-Shoshan, O., Wang, Y., & Bressler, L.J. (2010). Aggressive Treatment Style and Surgical Outcomes. *Health Services Research, 45*(6 Pt 2), 1872–1892.

We refer readers to CMS' QualityNet website: *https://qualitynet.cms.gov/inpatient/measures/psi* (or other successor CMS designated websites) for more details on the measure specifications.

(3) Measure Alignment to Strategy

The Failure-to-Rescue measure aligns with several goals under the CMS National Quality Strategy.[412] In alignment with the goal to ''Promote Alignment'' and ''Improved Health Outcomes,'' this outcome-based measure would allow hospitals to track their institution's ability to rescue patients after an adverse occurrence and encourage hospitals to focus on early identification and rapid treatment of complications, thereby improving the overall quality of care and health outcomes of patients in the inpatient setting. In alignment with the goal to ''Ensure Safe and Resilient Health Care Systems,'' the Failure-to-Rescue measure includes a larger patient population than the CMS PSI 04 measure. The Failure-to-Rescue measure includes Medicare Advantage data and the denominator includes a much broader range of hospital-acquired complications (for example, kidney dysfunction, seizures, stroke, heart failure, and wound infection) than the CMS PSI 04 measure.

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to section IX.B.1.c. of the preamble of this proposed rule for details on the PRMR process including the voting procedures the PRMR process uses to reach consensus on measure recommendations. The PRMR Hospital Committee, comprised of the PRMR Hospital Advisory Group and PRMR Hospital Recommendation Group, reviewed measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List),[413] [414] including the Failure-to-Rescue measure (MUC2023–049). The PRMR Hospital Recommendation Group reviewed the proposed updates to the Failure-to-Rescue measure (MUC2023–049) during a meeting on January 18–19, 2024.[415] [416]

The committee reached consensus and recommended including this measure in the Hospital IQR Program with conditions. Twelve members of the group voted to adopt the measure into the Hospital IQR Program without conditions; five members voted to adopt with conditions; two committee members voted not to recommend the measure for adoption. Taken together, 89.5 percent of the votes were recommend or recommended with conditions. The five members of the voting committee who voted to adopt with conditions specified the condition as collecting data to evaluate possible unintended consequences, such as hospitals encouraging patients to sign a DNR order or enter hospice. We agree with the potential for unintended consequences and note that we consistently monitor all of the measures in the Hospital IQR Program for unintended consequences. Furthermore, we note that under our previously finalized measure removal Factor 6, collection or reporting of a measure leads to negative unintended consequences other than patient harm, if we were to identify unintended consequences related to this measure we would consider it for removal.

Feedback was generally positive with some discussion around whether the measure was enough of an improvement on CMS PSI 04. The measure developer highlighted several areas of improvement compared to CMS PSI 04, including increased reliability and validity largely due to the application of this measure to both Medicare Advantage and fee-for-service enrollees, as well as the inclusion of deaths after hospital discharge but within 30 days of the index operative procedure.[417]

(b) Measure Endorsement

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees uses to evaluate measures and whether they meet endorsement criteria. The E&M Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health Committee convened in the Fall Cycle 2023 to review the Failure-to-Rescue measure (CBE #4125) which was submitted to the CBE for endorsement. The E&M Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health Committee ultimately voted to endorse with conditions on January 29th, 2024.[418] The condition was: perform additional reliability testing for endorsement review, namely conducting additional simulation analyses of minimum case volume adjustments.[419] We would monitor the data as part of the standard measure maintenance.

(5) Measure Calculation

The measure is calculated using Medicare fee-for-service (FFS) Part A inpatient claims data and Medicare Inpatient Encounter data for Medicare Advantage enrollees, in combination with validated death data from the Medicare Beneficiary Summary File or equivalent resources. CMS receives death information from a number of sources: Medicare claims data from the Medicare Common Working File (CWF); online date of death edits submitted by family members; and benefit information used to administer the Medicare program collected from the Railroad Retirement Board (RRB) and the Social Security Administration (SSA). Similar to the CMS 30-day mortality measures, the ''Valid Date of Death Switch'' is used to confirm that the exact day of death has been validated.

This measure was tested using Medicare inpatient hospital discharge data from 2,055 IPPS hospitals with at least 25 eligible discharges from January 1, 2021 through June 30, 2022. Hospital-level performance rates are depicted in

[412] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[413] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[414] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[415] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[416] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[417] Battelle—Partnership for Quality Measurement. (February 2024). 2023 Pre-Rulemaking Measure Review (PRMR) Meeting Summary: Hospital Committee. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary-Final.pdf.*

[418] Battelle—Partnership for Quality Measurement. (February 2024). Fall 2023 Management of Acute and Chronic Events Meeting Summary. Available at: *https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events,%20Chronic%20Disease,%20Surgery,%20and%20Behavioral%20Health/material/EM-Acute-Chronic-Events-Fall2023-Endorsement-Meeting-Summary.pdf.*

[419] Battelle—Partnership for Quality Measurement. (February 2024). Fall 2023 Management of Acute and Chronic Events Meeting Summary. Available at: *https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events,%20Chronic%20Disease,%20Surgery,%20and%20Behavioral%20Health/material/EM-Acute-Chronic-Events-Fall2023-Endorsement-Meeting-Summary.pdf.*

Table IX.C–2.[420] Because lower scores are better the lower performance percentiles are better performing hospitals than those in the higher percentiles (for example, the hospitals in the fifth percentile are the best performing hospitals).

TABLE IX.C.2 HOSPITAL PERFORMANCE IN MEASURE TESTING FOR THE FAILURE-TO-RESCUE MEASURE

Performance Percentile	Deaths per 1,000
5th	0
25th	29.33
Weighted mean	43.5
75th	60.95
95th	98.0

If hospitals currently in the worst quartile (that is, those at the 75th percentile) were to improve performance to the performance of hospitals in the best quartile (that is, those at the 25th percentile) it would represent a 50 percent decrease in the frequency of deaths after postoperative complications at those hospitals.[421]

Test results indicated moderate measure reliability and strong validity.[422]

(6) Data Submission and Reporting

This measure uses readily available administrative claims data routinely generated and submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare fee-for-service patients. Hospitals would not be required to report any additional data. We have used a similarly designed claims-based measure (CMS PSI 04) for over a decade. The Failure-to-Rescue measure would be calculated and publicly reported on annual basis using a rolling 24 months of prior data for the measurement period, consistent with the approach currently used for CMS PSI 04 and PSI 90, the Patient Safety and Adverse Events Composite.

We invite public comment on our proposal to adopt the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the CY 2025 reporting period/FY 2027 payment determination.

6. Proposed Measure Removals for the Hospital IQR Program Measure Set

We are proposing to remove five measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination; (2) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (3) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (4) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; and (5) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2021–March 31, 2024 reporting period/FY 2026 payment determination. We provide more details on each of these proposals in the subsequent sections.

a. Proposal To Remove the Death Among Surgical Inpatients With Serious Treatable Complications (CMS PSI 04) Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

We are proposing to remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure, beginning with the FY 2027 payment determination associated with the performance period of July 1, 2023–June 30, 2025, based on removal Factor 3,[423] the availability of a more broadly applicable measure (across settings, populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic. The CMS PSI 04 measure was adopted into the Hospital IQR Program in the FY 2009 IPPS/LTCH PPS final rule (73 FR 48607). The CMS PSI 04 measure records in-hospital deaths per 1,000 elective surgical discharges, among patients ages 18 through 89 years old or obstetric patients with serious treatable complications (shock/cardiac arrest, sepsis, pneumonia, deep vein thrombosis/pulmonary embolism, or gastrointestinal hemorrhage/acute ulcer).[424] It is a claims-based measure which uses claims and administrative data to calculate the measure without any additional data collection from hospitals. The measure was previously endorsed (CBE #0351), but given the measurement's limitations, endorsement was not maintained by the measure steward, and the measure has not been updated since 2017.[425]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25579 through 25580), we proposed to remove this measure under removal Factor 3, noting at that time that the Hybrid Hospital-Wide Mortality measure (Hybrid HWM) (CBE #3502) was more broadly applicable. Some public commenters, however, expressed concerns about replacing CMS PSI 04 with the Hybrid HWM measure since the Hybrid HWM measure would report on the mortality

[420] Battelle—Partnership for Quality Measurement. Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue). Available at: *https://p4qm.org/measures/4125*.

[421] Ibid.

[422] Ibid.

[423] We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal Factors. Removal Factors were codified at § 412.140. (88 FR 59144).

[424] Agency for Healthcare Research and Quality. (2023). AHRQ Quality Indicators™ (AHRQ QI™) ICD–9–CM Specification Version 6.0. Available at: *https://qualityindicators.ahrq.gov/Downloads/Modules/PSI/V2023/TechSpecs/PSI_04_Death_Rate_among_Surgical_Inpatients_with_Serious_Treatable_Complications.pdf*.

[425] Partnership for Quality Measurement. (2023). Death Rate among Surgical Inpatients with Serious Treatable Complications (PSI 04). Available at: *https://p4qm.org/measures/0351*.

rate of the entire hospital, instead of specifically measuring the deaths of surgical inpatients in an effort to assess postoperative mortality distinct from hospital-wide mortality (86 FR 45391). Other commenters elaborated on this concern stating that by removing a postoperative-specific mortality measure, hospitals may lose the ability to account for what resources they need to better care for surgical inpatients since that population's needs often differs from the needs of non-surgical IPPS hospital patients (86 FR 45391 through 45392).[426] Some commenters suggested modifications to the existing CMS PSI 04 measure such as changing its methodology to refine the types of surgical patients and complications included in the measure and to expand the measure beyond surgical inpatients (86 FR 45390 through 45391). Other commenters suggested keeping CMS PSI 04 unchanged because of the importance of evaluating patient deaths when assessing patient safety and suggested adding more patient safety measures to the Hospital IQR Program measure set, expressing their belief that there were too few patient safety measures in the program (86 FR 45391). After consideration of the public comments on our proposal to remove CMS PSI 04 in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25579 through 25580) we decided not to finalize removal of the measure at that time.

Since then, we have developed the Thirty-Day Risk-Standardized Death Rate Among Surgical Inpatients with Complications (Failure-to-Rescue) (CBE #4125) measure, as proposed for adoption in section IX.C.5.e. of this proposed rule beginning with the FY 2027 payment determination. The Failure-to-Rescue measure is a more broadly applicable measure that would be more appropriate for inclusion in the Hospital IQR Program. Recent studies have indicated that the CMS PSI 04 measure does not consistently recognize preventable in-hospital deaths (failure to rescue cases). A 2023 study indicated that CMS PSI 04 is being used to an unknown extent outside of postoperative cases, and there is often erroneous categorization of patients as having a CMS PSI 04 complication.[427] This same study found significant variation in the identification of CMS PSI 04 complications at different procedure locations (For example: bedside versus operating room procedures).[428] Therefore, both the temporal and causal relationship attributing a CMS PSI 04 complication to patient mortality has been found to be poorly understood, particularly because CMS PSI 04 relates to a complication being deemed treatable.[429]

We are proposing to adopt the Failure-to-Rescue measure to replace CMS PSI 04 as a more broadly applicable patient safety indicator and one which can better address concerns previously raised by interested parties. The Failure-to-Rescue measure assesses the percentage of surgical inpatients who experienced a complication and then died within 30-days from the date of their first ''operating room'' procedure. We refer readers to section IX.C.5.e. of this proposed rule for more detail on the Failure-to-Rescue measure including the timeline for its initial performance, reporting, and payment determination periods.

While CMS PSI 04 only measures the rate of in-hospital deaths among surgical inpatients within a set of serious treatable conditions, the Failure-to-Rescue measure assesses the probability of death given a postoperative complication and is inclusive of a broader range of conditions commonly experienced by surgical inpatients. To best address the needs of a broader scope of surgical inpatients and conditions, it allows for more context-specific approaches to measure preventable deaths due to the highly variable nature of surgical procedures between specialties. This highly variable and context-specific nature of postoperative cases has been considered a challenge of using CMS PSI 04 as an effective universal patient safety metric.[430] There would be minimal burden for hospitals associated with replacing CMS PSI 04 with the Failure-to-Rescue measure due to the Failure-to Rescue measure's data sources, including its use of Medicare Advantage encounter data. Thus, the Failure-to-Rescue measure would include a wider range of patients and better reflect the true nature of postoperative patient safety at institutions. In addition, multiple failure-to-rescue measures have been repeatedly validated by their consistent association with nurse staffing, nursing skill mix, technological resources, rapid response systems, and other activities that improve early identification and prompt intervention when complications arise after surgery.[431] [432] [433]

By using the Failure-to-Rescue measure, hospitals can identify opportunities to improve their quality of care and patient safety. Hospitals and healthcare providers can benefit from knowing not only their institution's mortality rate, but also their institution's ability to provide each patient with the appropriate and necessary standard of care after an adverse occurrence.[434] Using the Failure-to-Rescue measure as opposed to the current CMS PSI 04 measure is especially important if the hospital resources needed for preventing and treating 30-day postoperative complications among surgical inpatients are different from those needed for targeted care after an adverse event, such as more skilled care personnel or equipment specific to postoperative care. From a quality improvement perspective, the Failure-to-Rescue measure rate would complement the mortality rate to improve our understanding of mortality statistics and identify opportunities for improvement.[435] Therefore, the quality-of-care measurement may be improved if both mortality and Failure-to-Rescue measure rates are reported instead of relying on the Hybrid HWM measure alone. Using the Failure-to-Rescue measure instead of the CMS PSI 04 measure would allow us to assess an

[426] Nilsson, U., Gruen, R., & Myles, P. S. (2020). Postoperative recovery: The importance of the team. Anesthesia, 75(S1). *https://doi.org/10.1111/anae.14869.*

[427] Azad, T.D., Rodriguez, E., Raj, D., Xia, Y., Materi, J., Rincon-Torroella, J., Gonzalez, L.F., Suarez, J.I., Tamargo, R.J., Brem, H., Haut, E.R., & Bettegowda, C. (2023). Patient Safety Indicator 04 Does Not Consistently Identify Failure to Rescue in the Neurosurgical Population. Neurosurgery, 92(2), 338–343. *https://doi.org/10.1227/neu.0000000000002204.*

[428] Ibid

[429] Ibid.

[430] Azad, T.D., Rodriguez, E., Raj, D., Xia, Y., Materi, J., Rincon-Torroella, J., Gonzalez, L.F., Suarez, J.I., Tamargo, R.J., Brem, H., Haut, E.R., & Bettegowda, C. (2023). Patient Safety Indicator 04 Does Not Consistently Identify Failure to Rescue in the Neurosurgical Population. Neurosurgery, 92(2), 338–343. *https://doi.org/10.1227/neu.0000000000002204.*

[431] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[432] Rosero, E.B., Romito, B.T., & Joshi, G.P. (2021). Failure to rescue: A quality indicator for postoperative care. Best Practice & Research Clinical Anesthesiology, 35(4), 575–589. *https://doi.org/10.1016/j.bpa.2020.09.003.*

[433] Hall K.K., Lim A., Gale B. Failure To Rescue. In: Hall K.K., Shoemaker-Hunt S., Hoffman L., et al. Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020 Mar. 2. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK555513/.*

[434] Rodziewicz T.L., Houseman B., Hipskind J.E. Medical Error Reduction and Prevention. [Updated 2023 May 2]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK499956/.*

[435] Ward, S.T., Dimick, J.B., Zhang, W., Campbell, D.A., & Ghaferi, A.A. (2019). Association Between Hospital Staffing Models and Failure to Rescue. Annals of surgery, 270(1), 91–94. *https://doi.org/10.1097/SLA.0000000000002744.*

expanded population and encourage safe practices for the widest range of surgical inpatients.

We are proposing to remove the CMS PSI 04 measure from the Hospital IQR Program beginning with the FY 2027 payment determination associated with the performance period of July 1, 2023–June 30, 2025, contingent upon finalizing our proposal to adopt the Failure-to-Rescue measure beginning with the FY 2027 payment determination so that there is no gap in measuring this important topic area.

We invite public comment on our proposal to remove the CMS PSI 04 measure from the Hospital IQR Program beginning with the FY 2027 payment determination associated with the performance period of July 1, 2023–June 30, 2025, contingent upon finalizing our proposal to adopt the Failure-to-Rescue measure beginning with the FY 2027 payment determination.

b. Proposal To Remove Four Clinical Episode-Based Payment Measures Beginning With the FY 2026 Payment Determination

We are proposing to remove four clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2026 payment determination:

- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction (AMI) (CBE #2431) (AMI Payment) (adopted at 78 FR 50802 through 50805). This measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for acute myocardial infarction for Medicare FFS patients aged 65 or older for any hospital participating in the Hospital IQR Program;
- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure (HF) (CBE #2436) (HF Payment) (adopted at 79 FR 50231 through 50235). This measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for heart failure for Medicare FFS patients aged 65 or older for any hospital participating in the Hospital IQR Program;
- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia (PN) (CBE #2579) (PN Payment) (adopted at 79 FR 50227 through 50231). This measure assesses hospital risk-standardized payment associated with a 30-day episode-of-care for pneumonia for any hospital participating in the Hospital IQR Program and includes Medicare FFS patients aged 65 or older; and
- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CBE #3474) (THA/TKA Payment) (adopted at 80 FR 49674 through 49680; revised at 87 FR 49267 through 49269). This measure assesses hospital risk-standardized payment (including payments made by CMS, patients, and other insurers) associated with a 90-day episode-of-care for elective primary THA/TKA for any hospital participating in the Hospital IQR Program and includes Medicare FFS patients aged 65 or older.

The proposed final performance periods for these four payment measures are indicated in the following table:

TABLE IX.C.3. Proposed Final Performance Period & Payment Determination for AMI Payment, HF Payment, PN Payment, and /TKA Payment Measures

Measure	Performance Period	Payment Determination
AMI Payment	July 1, 2021 – June 30, 2024	FY 2026
HF Payment	July 1, 2021 – June 30, 2024	FY 2026
PN Payment	July 1, 2021 – June 30, 2024	FY 2026
THA/TKA Payment	April 1, 2021 – March 31, 2024	FY 2026

We are proposing to remove the AMI Payment, HF Payment, PN Payment, and THA/TKA Payment measures under measure removal Factor 3, the availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic)—specifically, the Medicare Spending Per Beneficiary Hospital measure (CBE #2158) (MSPB Hospital measure) in the Hospital VBP Program.[436] The MSPB Hospital measure has been intermittently included in the Hospital IQR Program's measure set, most recently to update the measure specifications in the Hospital VBP Program. The Hospital VBP Program's statute requires that measures be publicly reported for one year in the Hospital IQR Program prior to the beginning of the performance period in the Hospital VBP Program (section 1886(o)(2)(B)(ii) of the Act and 42 CFR 412.164(b)).[437] In the FY 2023 IPPS/LTCH PPS final rule, we re-adopted the previously removed MSPB Hospital measure into the Hospital IQR Program with refinements (87 FR 28529 through 28532) to update the measure specifications for purposes of the Hospital VBP Program. We subsequently removed it again from the Hospital IQR Program and concurrently adopted the refined version into the Hospital VBP Program (88 FR 59064 through 59067, 59170 through 59171, respectively). We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263) for more details on this measure's history in the Hospital IQR and Hospital VBP Programs.

The MSPB Hospital measure evaluates hospitals' efficiency and resource use relative to the efficiency of the national median hospital. The MSPB Hospital measure is a more broadly applicable measure because it captures the same data as the four clinical episode-based payment measures being proposed for removal but incorporates a much larger set of conditions and procedures. We note that we recently adopted refinements to the MSPB

[436] We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal Factors. Removal Factors were codified at § 412.140. (88 FR 59144).

[437] When substantive updates to measure specifications are needed, we have had to readopt the measure and updates into the Hospital IQR Program first. The measure was initially adopted into the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618) and then was finalized for removal in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41559 through 41560) to deduplicate the measure sets across programs and reduce burden for hospitals.

Hospital measure to ensure a more comprehensive and consistent assessment of hospital performance (87 FR 49257 through 49263, 88 FR 59064 through 59067). Those refinements allow the measure to capture more episodes and adjusted the measure calculation.[438]

The four clinical episode-based payment measures being proposed for removal are condition-specific whereas the MSPB Hospital measure is not. Although the MSPB Hospital measure does not provide the same level of granularity as the four condition-specific measures, the important data elements would be captured more broadly under the Hospital VBP Program by evaluating and publicly reporting the hospitals' efficiency relative to the efficiency of the median national hospital. Specifically, the MSPB Hospital measure assesses the cost to Medicare for services performed by hospitals and other healthcare providers during an episode of care, which includes the three days prior to, during, and 30 days following an inpatient's hospital stay.[439] Additionally, providers will continue to receive confidential feedback reports containing details on the MSPB Hospital measure.

We note that performance on these four clinical episode-based payment measures has either remained stable or decreased since FY 2019. Based on an internal CMS analysis, the mean performance for the PN Payment, HF Payment, and AMI Payment measures has decreased, while the mean performance for the THA/TKA Payment measure has remained stable. Considering these performance trends, we highlight that these four clinical episode-based payment measures have not been as beneficial in recent years to the Hospital IQR Program.

We invite public comment on our proposal to remove these four clinical episode-based payment measures from the Hospital IQR Program beginning with the FY 2026 payment determination.

7. Proposed Refinements to Current Measures in the Hospital IQR Program Measure Set

We are proposing refinements to two measures currently in the Hospital IQR Program measure set: (1) Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination and for subsequent year, and (2) the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure beginning with the CY 2025 reporting period/FY 2027 payment determination. We provide more details on the GMCS eCQM proposal in the subsequent sections and details on the proposed modification to HCAHPS Survey measure are in section IX.B.2.e. of this proposed rule.

a. Proposal To Modify the Global Malnutrition Composite Score Measure Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

(1) Background

The previously finalized GMCS eCQM (CBE #3592e) assesses the percentage of hospitalizations for adults 65 years old and older prior to the start of the measurement period with a length of stay equal to or greater than 24 hours who received optimal malnutrition care during the current inpatient hospitalizations where care performed was appropriate to the patient's level of malnutrition risk and severity. We adopted the GMCS eCQM in the FY 2023 IPPS/LTCH PPS final rule beginning with the CY 2024 reporting period/FY 2026 payment determination (87 FR 49239 through 49246). We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49241 through 49242) for more detailed discussion of the CBE review and endorsement of the current GMCS eCQM, which received CBE endorsement in July 2021 (CBE #3592e).[440] [441]

While we understand the unique challenges malnutrition creates for older adults, we also recognize that hospital and disease-related malnutrition is not limited to that population (87 FR 49239). Data from the Agency for Healthcare Research and Quality (AHRQ) indicate that approximately eight percent of all hospitalized adults have a diagnosis of malnutrition,[442] and additional research finds that malnutrition and malnutrition risk can be found in 20 to 50 percent of hospitalized adults 18 years old and older.[443] Failure to diagnose and insufficient treatment of malnutrition in hospitals is also associated with poor institutional coordination between nurses, physicians, and other hospital staff regarding screening, diagnosis, and treatment, further emphasizing the need to address malnutrition in all hospitalized adults.[444] Because malnutrition impacts adults of all ages, preventive screening and intervention among all hospitalized adults 18 years old and older would greatly reduce the risk and improve the treatment of malnutrition.[445] A 2020 study estimated that every dollar spent on nutrition interventions in a hospital setting can result in up to $99 in savings on subsequent medical care.[446] Screening all patients over age 18 for malnutrition instead of only those over age 65 could result in both improved clinical outcomes for patients and substantial financial savings for the healthcare system.

Therefore, in this proposed rule, we are proposing to modify the GMCS eCQM to expand the applicable population from hospitalized adults 65 or older to hospitalized adults 18 or older. The modified GMCS eCQM would broaden the measure to assess hospitalized adults 18 years old and older who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified.

(2) Measure Alignment to Strategy

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49239), we noted that the adoption of a malnutrition measure may help address several priority areas identified in the CMS Framework for

[438] These refinements are available in a summary of the measure re-evaluation on the CMS QualityNet website, Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/hvbp-mspb.*

[439] Centers for Medicare & Medicaid Services. (2023). Medicare Spending Per Beneficiary—National *https://data.cms.gov/provider-data/dataset/3n5g-6b7f.*

[440] Partnership for Quality Measurement. (2023). Global Malnutrition Composite Score. Available at: *https://p4qm.org/measures/3592e.*

[441] Centers for Medicare & Medicaid Services Measures Inventory Tool. (2023). Global Malnutrition Composite Score. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=5120&sectionNumber=1.*

[442] United States Agency for Healthcare Research and Quality. (2016). Non-maternal and non-neonatal inpatient stays in the United States involving malnutrition 2016. Available at: *https://hcup-us.ahrq.gov/reports/ataglance/HCUPMalnutritionHospReport_083018.pdf.*

[443] Kabashneh, S., Alkassis, S., Shanah, L., & Ali, H. (2020). A Complete Guide to Identify and Manage Malnutrition in Hospitalized Patients. *Cureus, 12*(6), e8486. *https://doi.org/10.7759/cureus.8486.*

[444] Anghel, S., Kerr, K.W., Valladares, A.F., Kilgore, K.M., & Sulo, S. (2021). Identifying patients with malnutrition and improving use of nutrition interventions: A quality study in four US hospitals. Nutrition, 91–92, 111360. *https://doi.org/10.1016/j.nut.2021.111360.*

[445] Sauer, A.C., Goates, S., Malone, A., Mogensen, K.M., Gewirtz, G., Sulz, I., Moick, S., Laviano, A., & Hiesmayr, M. (2019). Prevalence of malnutrition risk and the impact of nutrition risk on hospital outcomes: Results from nutrition day in the U.S. Journal of Parenteral and Enteral Nutrition, 43(7), 918–926. *https://doi.org/10.1002/jpen.1499.*

[446] Suela Sulo, Leah Gramlich, Jyoti Benjamin, Sharon McCauley, Jan Powers, Krishnan Sriram & Kristi Mitchell (2020) Nutrition Interventions Deliver Value in Healthcare: Real-World Evidence, Nutrition and Dietary Supplements, 12:, 139–146, DOI: 10.2147/NDS.S262364.

Health Equity [447] (87 FR 49240 through 49241) and expanding the current measure's population to include all adults over 18 years old would further address these priorities. Malnutrition in the U.S., whether caused by challenges from disease and functional limitations, food insecurity, other factors, or a combination of causes, is more frequently experienced by underserved populations and can thus be a contributing factor to health inequities.[448] Adopting the updated measure as proposed would lead to a more diverse population being assessed for malnutrition, and by identifying instances of malnutrition among younger populations, the benefits of proper nutrition could be felt over a lifetime. As part of the CMS National Quality Strategy, the modified GMCS eCQM would also address the priority area of ''Promote Aligned and Improved Health Outcomes.'' [449] Under the CMS Meaningful Measures 2.0 Initiative, which is a key component of the CMS National Quality Strategy, the modified GMCS eCQM addresses the quality priorities of ''Seamless Care Coordination,'' ''Person-Centered Care,'' and ''Equity.'' It would address these priorities by connecting providers at different levels of care to ensure the largest possible population of adult patients with in-hospital malnutrition are identified and treated using a patient-centered approach.

(3) Overview of Measure Update

The modified GMCS eCQM still includes the four component measures corresponding to documented best practices as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49241) and in the first column of Table IX.C.4. The only change we are proposing is to expand the applicable population for this measure. The measure specifications for the modified GMCS eCQM can be found on the eCQI Resource Center website, available at: *https://ecqi.healthit.gov/ecqm/eh/2024/cms0986v2.*

(4) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to the proposed Patient Safety Structural measure in section IX.B.1.c. of this proposed rule for details on the PRMR process including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 18–19, 2024, to review measures included by the Secretary on a publicly available ''2023 Measures Under Consideration List'' (MUC List),[450] [451] including the modified GMCS eCQM (MUC2023–114), to vote on a recommendation with regard to use of this measure.[452] [453]

The PRMR Hospital Committee reached consensus and recommended including this measure (MUC2023–114) in the Hospital IQR Program with conditions. Fourteen members of the group recommended adopting the measure into the Hospital IQR Program without conditions; three members recommended adoption with conditions; two committee members voted not to recommend the measure for adoption. Taken together, 84.2 percent of the votes were recommended with conditions.[454] The three members who voted to adopt with conditions specified the condition as screening and assessment includes hospital-acquired malnutrition and high-risk nutritional practices in hospitals, such as prolonged fasting for rescheduled procedures, and to obtain more feedback from patient groups. We agree that the potential for unintended consequences exists and note that we consistently monitor all of the measures in the Hospital IQR Program for unintended consequences. Furthermore, we note that under our previously finalized measure removal Factor 6, collection or public reporting of a measure leads to negative unintended consequences other than patient harm, if we were to identify unintended consequences related to this measure, we would consider it for removal.

(b) Measure Endorsement

We refer readers to section IX.B.1.c. of the preamble of this proposed rule for details on the E&M process including the measure evaluation procedures the E&M Committees, comprised of the E&M Advisory Group and E&M Recommendation Group, uses to evaluate measures and whether they meet endorsement criteria. The GMCS eCQM was initially endorsed in the Fall 2020 cycle by the CBE (CBE #3592e) and is scheduled for endorsement review with the proposed modification in 2024.[455] Section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Here, after reviewing the current measure, we found no measures, other than the current GMCS measure, on this topic. We have determined this is an appropriate medical topic for us to propose the adoption of an unendorsed measure because of its general consistency with the current, endorsed measure, and the usefulness of the measure would be substantially improved by the proposed modification.

(5) Measure Calculation

The modified GMCS eCQM would still use data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS.

The modified GMCS eCQM continues to consist of four component measures,

[447] Centers for Medicare & Medicaid Services. (2023). CMS Framework for Health Equity. Available at: *https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework.*

[448] Blankenship, J., & Blancato, R.B. (2022). Nutrition Security at the Intersection of Health Equity and Quality Care. Journal of the Academy of Nutrition and Dietetics, 122(10S), S12–S19. *https://doi.org/10.1016/j.jand.2022.06.017.*

[449] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy. Available at: *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

[450] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[451] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[452] Centers for Medicare & Medicaid Services. 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[453] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

[454] Battelle—Partnership for Quality Measurement. (February 2024). Pre-Rulemaking Measure Review Measures Under Consideration 2023 RECOMMENDATIONS REPORT. Available at: *https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf.*

[455] Battelle—Partnership for Quality Measurement. Global Malnutrition Composite Score eCQM. Available at: *https://p4qm.org/measures/3592e.*

which are first scored separately.[456] [457] The overall composite score is derived from averaging the individual performance scores of the four component measures. The malnutrition component measures are all fully specified for use in EHRs. Table IX.C.4 describes each of the four measure components with the proposed expanded population.

TABLE IX.C.4 . MODIFIED GLOBAL MALNUTRITION COMPOSITE SCORE ECQM COMPONENTS' MEASURE DESCRIPTIONS

Component	Measure Observation
Completion of a Malnutrition Screening.	Patients 18 years old and older in the denominator who have a malnutrition screening documented in the medical record.
Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition.	Patients 18 years old and older in the denominator who have a nutrition assessment documented in the medical record.
Appropriate Documentation of a Malnutrition Diagnosis.	Patients 18 years old and older in the denominator with a diagnosis of malnutrition documented in the medical record.
Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment.	Patients 18 years old and older in the denominator who have a nutrition care plan documented in the medical record.

The modified GMCS eCQM numerator is comprised of the four component measures, that are individually scored for patients 18 years old and older who are admitted to an acute inpatient hospital. The measure denominator is the composite, or total, of the four component measures for patients 18 years old and older who are admitted to an acute inpatient hospital. The only exclusion for this measure population remains as patients whose length of stay is less than 24 hours, the same as previously adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49244).

Each measure component is a proportion with a possible performance score of 0 to 100 percent (higher percent reflects better performance). After each component score is calculated individually, an unweighted average of all four scores is computed to determine the final composite score for the individual with a total score ranging from 0 to 100 percent (higher percent reflects better performance).[458]

(6) Data Submission and Reporting

We are proposing the adoption of the modified GMCS eCQM as part of the Hospital IQR Program measure set from which hospitals can self-select beginning with the CY 2026 reporting period/FY 2028 payment determination. Since this modification uses the same data sources and collection methods as the current version of the GMCS eCQM, there is not expected to be any major impact to workflows or other aspects of data collection. The only anticipated change to data collection processes is that the data would be collected from a larger patient population. We refer readers to section XI.C.9.c. of this proposed rule for our previously finalized eCQM reporting and submission requirements, as well as proposed modifications for these requirements.

We also refer readers to section IX.F.6.a.(2). of the preamble of this proposed rule for discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs.

We invite public comment on our proposal to modify the GMCS eCQM to expand the applicable population from hospitalized adults 65 years old or older to hospitalized adults 18 years old or older beginning with the CY 2026 reporting period/FY 2028 payment determination.

8. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2026 Payment Determination

This table summarizes the previously finalized Hospital IQR Program measure set for the FY 2026 payment determination including the proposed removals of four claims-based payment measures:

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[456] Valladares A.F., McCauley S.M., Khan M., D'Andrea C., Kilgore K., Mitchell K. Development and Evaluation of a Global Malnutrition Composite Score. J Acad Nutr Diet. 2022 Feb;122(2):251–258. doi: 10.1016/j.jand.2021.02.002. Epub 2021 Mar 10. PMID: 33714687.

[457] Centers for Medicare & Medicaid Services Measures Inventory Tool. (2023). Global Malnutrition Composite Score. Available at: *https://cmit.cms.gov/cmit/#/.*

[458] Centers for Medicare & Medicaid Services Measures Inventory Tool. (2023). Global Malnutrition Composite Score. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=5120&sectionNumber=1.*

TABLE IX.C.5. MEASURES FOR THE FY 2026 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
CMS PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality-Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWM*	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia Measure	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia Measure	3533e
HH-ORAE	Hospital Harm - Opioid-Related Adverse Events	3501e
GMCS	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In the FY 2022 IPPS/LTCH PPS final rule we finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the July 1, 2023-June 30, 2024 reporting period, impacting the FY 2026 payment determination (86 FR 45365 through 45374).

** In the FY 2020 IPPS/LTCH PPS final rule, we finalized removal of the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (CBE #1789) and will replace it with the Hybrid HWR measure (CBE #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). In the FY 2024 IPPS/LTCH PPS final rule, we finalized refinements to these measures beginning with the FY 2027 payment determination (88 FR 59161 through 59168).

b. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the previously finalized Hospital IQR Program measure set for the FY 2027 payment determination including the proposed adoption of two new structural measures, one new claims-based patient safety measure, and the proposed removal of the CMS PSI 04 measure:

TABLE IX.C.6. MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
FTR*	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) Measure	4125
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality-Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWM	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Age Friendly Hospital**	Age Friendly Hospital Measure	N/A
Patient Safety***	Patient Safety Structural Measure	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371

Short Name	Measure Name	CBE #
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia Measure	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia Measure	3533e
HH-OREA	Hospital Harm - Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm - Pressure Injury	3498e
HH-AKI	Hospital Harm - Acute Kidney Injury	3713e
GMCS	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults	3663e
Patient Experience of Care Survey Measures		
HCAHPS****	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure and its replacement with the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.e. for more detailed discussion.

** In this proposed rule, we are proposing adoption of the Age Friendly Hospital measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.a. for more detailed discussion.

*** In this proposed rule, we are proposing adoption of the Patient Safety Structural measure beginning with the FY 2027 payment determination. We refer readers to section IX.B.1. for more detailed discussion.

**** In this proposed rule, we are proposing refinements to the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure) measure beginning with the FY 2027 payment determination. We refer readers to section IX.B.2.e. for more detailed discussion.

c. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2028 Payment Determination

This table summarizes the previously finalized and proposed Hospital IQR Program measure set for the FY 2028 payment determination including the proposed adoption of two new Hospital Harm measures, two new NHSN measures, proposed modification of the GMCS eCQM, and the proposed Updated Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure):

TABLE IX.C.7. MEASURES FOR THE FY 2028 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Healthcare Personnel	3636
CAUTI-Onc*	Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations	0138
CLABSI-Onc**	Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations	0139
Claims-Based Patient Safety Measures		
FTR***	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue)	4125
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary TIIA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims and Electronic Data Measures		
Hybrid HWM	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Age Friendly Hospital****	Age Friendly Hospital Measure	N/A
Patient Safety*****	Patient Safety Structural Measure	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia Measure	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia Measure	3533e
HH-OREA	Hospital Harm - Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm - Pressure Injury	3498e
HH-AKI	Hospital Harm - Acute Kidney Injury	3713e
HH-FI******	Hospital Harm - Falls with Injury	4120e
HH-RF*******	Hospital Harm - Postoperative Respiratory Failure	4130e
GMCS********	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults	3663e
Patient Experience of Care Survey Measures		
HCAHPS*********	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of the Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.b.(1). for more detailed discussion.

** In this proposed rule, we are proposing adoption of the Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.b.(2). for more detailed discussion.

*** In this proposed rule, we are proposing removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure and its replacement with the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.e. for more detailed discussion.
**** In this proposed rule, we are proposing adoption of the Age Friendly Hospital measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.a. for more detailed discussion.
***** In this proposed rule, we are proposing adoption of the Patient Safety Structural measure beginning with the FY 2027 payment determination. We refer readers to section IX.B.1. for more detailed discussion.
****** In this proposed rule, we are proposing adoption of the Hospital Harm - Falls with Injury eCQM beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.c. for more detailed discussion.
******* In this proposed rule, we are proposing adoption of the Hospital Harm - Postoperative Respiratory Failure eCQM beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.d. for more detailed discussion.
******** In this proposed rule, we are proposing refinements to the Global Malnutrition Composite Score (GMCS) measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.7.a. for more detailed discussion.
********* In this proposed rule, we are proposing refinements to the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure) measure beginning with the FY 2027 payment determination. We refer readers to section IX.B.2.e. for more detailed discussion.

d. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2029 Payment Determination and for Subsequent Years

This table summarizes the previously finalized and proposed Hospital IQR Program measure set for the FY 2029 payment determination and for subsequent years:

TABLE IX.C.8. MEASURES FOR THE FY 2029 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination	COVID-19 Vaccination Coverage Among Healthcare Personnel	3636
CAUTI-Onc*	Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations	0138
CLABSI-Onc**	Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations	0139
Claims-Based Patient Safety Measures		
FTR***	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue)	4125
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims and Electronic Data Measures		
Hybrid HWM	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Hybrid HWR	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Age Friendly Hospital****	Age Friendly Hospital Measure	N/A
Patient Safety*****	Patient Safety Structural Measure	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia Measure	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia Measure	3533e
HH-OREA	Hospital Harm - Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm - Pressure Injury	3498e
HH-AKI	Hospital Harm - Acute Kidney Injury	3713e
HH-FI******	Hospital Harm - Falls with Injury	4120e
HH-RF*******	Hospital Harm - Postoperative Respiratory Failure	4130e
GMCS********	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults	3663e
Patient Experience of Care Survey Measures		
HCAHPS*********	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this proposed rule, we are proposing adoption of the Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.b.(1). for more detailed discussion.

** In this proposed rule, we are proposing adoption of the Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.b.(2). for more detailed discussion.

*** In this proposed rule, we are proposing removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure and its replacement with the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.e. for more detailed discussion.
**** In this proposed rule, we are proposing adoption of the Age Friendly Hospital measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.5.a. for more detailed discussion.
***** In this proposed rule, we are proposing adoption of the Patient Safety Structural measure beginning with the FY 2027 payment determination. We refer readers to section IX.B.1. for more detailed discussion.
****** In this proposed rule, we are proposing adoption of the Hospital Harm - Falls with Injury eCQM beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.c. for more detailed discussion.
******* In this proposed rule, we are proposing adoption of the Hospital Harm - Postoperative Respiratory Failure eCQM beginning with the FY 2028 payment determination. We refer readers to section IX.C.5.d. for more detailed discussion.
******** In this proposed rule, we are proposing we are proposing refinements to the Global Malnutrition Composite Score (GMCS) measure beginning with the FY 2028 payment determination. We refer readers to section IX.C.7.a. for more detailed discussion.
********* In this proposed rule, we are proposing refinements to the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure) measure beginning with the FY 2028 payment determination. We refer readers to section IX.B.2.e for more detailed discussion.

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9. Form, Manner, and Timing of Quality Data Submission

We are proposing changes to our reporting and submission requirements for eCQMs. There are no proposed changes to the following requirements, and thus have been omitted from the Form, Manner, and Timing of Quality Data Submission section: procedural requirements; data submission requirements for chart-abstracted measures; data submission and reporting requirements for hybrid measures; sampling and case thresholds for chart-abstracted measures; HCAHPS Survey administration and submission requirements; data submission requirements for structural measures; data submission and reporting requirements for CDC NHSN measures; and data submission and reporting requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs). We refer readers to the QualityNet website at: *https://qualitynet.cms.gov/inpatient/iqr* (or other successor CMS designated websites) for more details on the Hospital IQR Program data submission and procedural requirements.

a. Background

Section 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner and at a time specified by the Secretary. To successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.

b. Maintenance of Technical Specifications for Quality Measures

Section 412.140(c)(1) of title 42 of the Code of Federal Regulations generally requires that a subsection (d) hospital participating in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications for eCQMs. The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2024 reporting period/FY 2026 payment determination, hospitals are collecting and will submit eCQM data using the May 2023 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) (42 CFR 412.140(a)). The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

c. Reporting and Submission Requirements for eCQMs

We are proposing a progressive increase in the number of mandatory eCQMs a hospital must report beginning with the CY 2026 reporting period/FY 2028 payment determination. We are not proposing any changes to the current eCQM reporting or submission requirements for the CY 2024 reporting period/FY 2026 payment determination or the CY 2025 reporting period/FY 2027 payment determination. We provide additional detail in our proposal later in this section of the preamble.

(1) Background

We began requiring hospitals to report on eCQMs in the CY 2016 reporting period, with a goal of progressively increasing the number of eCQMs hospitals are required to report in the Hospital IQR Program while also being responsive to hospitals' concerns about timing, readiness, and burden associated with the increased number of measures (80 FR 49693 through 49698, and 81 FR 57150 through 57157). To allow hospitals and their vendors time

to gain experience with reporting eCQMs we gradually increased the number of eCQMs on which hospitals were required to report over the course of several years. We required hospitals to report on certain specific eCQMs that we prioritized while retaining an element of choice by allowing hospitals to self-select some eCQMs. We also gradually increased the number of reporting quarters to improve measure reliability for public reporting of performance information (84 FR 42503 through 42505, 85 FR 58932 through 58939, 86 FR 45418, and 87 FR 49299 through 49302).

Under our current eCQM reporting policies, hospitals must report four calendar quarters of data for each required eCQM: (1) the Safe Use of Opioids—Concurrent Prescribing eCQM; (2) the Cesarean Birth eCQM; (3) the Severe Obstetric Complications eCQM; and (4) three self-selected eCQMs; for a total of six eCQMs for the CY 2024 reporting period/FY 2026 payment determination and subsequent years (85 FR 58932 through 58939, 86 FR 45418, and 87 FR 49298 through 49302). We refer readers to the QualityNet website for additional information on current and previous reporting and submission requirements policies for eCQMs at: *https://qualitynet.cms.gov/inpatient/measures/ecqm* (or other successor CMS designated websites).

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized the revisions to the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4. Specifically, we finalized the addition of a reference to the revised name of ''Base EHR definition,'' proposed in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) proposed rule (88 FR 23759, 23905), to ensure, if the HTI–1 proposals were finalized, the revised name of ''Base EHR definition'' would be applicable for the CEHRT definitions going forward (88 FR 79309 through 79312). We also finalized the replacement of our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria,'' and the addition of the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We finalized the proposal to specify that technology meeting the CEHRT definition must meet ONC's health IT certification criteria ''as adopted and updated in 45 CFR 170.315'' (88 FR 79553). This approach is consistent with the definitions subsequently finalized in ONC's HTI–1 final rule, which appeared in the **Federal Register** on January 9, 2024 (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

(2) Proposal To Progressively Increase Mandatory eCQM Reporting Beginning With CY 2026 Reporting Period/FY2028 Payment Determination

Increasing the number of mandatory eCQMs, specifically to include the five previously adopted Hospital Harm eCQMs, would support our re-commitment to better safety practices for both patients and healthcare workers to save lives from preventable harms.[459] Proposing mandatory reporting of these Hospital Harms eCQMs are a part of our initial actions in responding and joining the President's Council of Advisors on Science and Technology (PCAST) call to action to renew ''our nation's commitment to improving patient safety.'' [460] We refer readers to section IX.B.1. for more details on other efforts toward better patient and healthcare workers safety practices and the proposal to adopt the Patient Safety Structural measure into the Hospital IQR Program and the PCHQR Program.

This proposal also aligns with CMS' National Quality Strategy priority area of ''Patient Safety and Resiliency,'' that seeks to ''improve performance on key patient safety metrics through the applications of CMS levers such as quality measurement, payment, health and safety standards, and quality improvement support.'' [461] It is important to more comprehensively collect data on these measures from all hospitals participating in the Hospital IQR Program instead of limiting data collection to just those hospitals that chose to report it. Capturing this important quality information is crucial to improve surveillance on safety metrics in the Hospital IQR Program and support the CMS National Quality Strategy target success goal of reducing preventable harm.[462] Additionally, this proposal aligns with the ''Interoperability'' goal outlined in the National Quality Strategy that eCQMs use standard and interoperable data requirements that are less burdensome than other types of measures. By increasing the number of required eCQMs, and prioritizing the measures focused on preventable hospital harms, we are progressing towards our goal of using all digital measures. Thus, we are proposing to increase the number of mandatory eCQMs over a two-year period to ultimately require reporting on five additional eCQMs. We provide additional details on the proposals later in this section of the preamble.

(a) Proposal To Change the Reporting and Submission Requirements for eCQMs for the CY 2026 Reporting Period/FY 2028 Payment Determination

Beginning with the CY 2026 reporting period/FY 2028 payment determination, we are proposing to modify the eCQM reporting and submission requirements to require hospitals to report on the following three eCQMs in addition to the existing eCQMs: (1) Hospital Harm—Severe Hypoglycemia eCQM; (2) Hospital Harm—Severe Hyperglycemia eCQM; and (3) Hospital Harm—Opioid-Related Adverse Events eCQM. If this proposal is finalized, beginning with the CY 2026 reporting period/FY 2028 payment determination, hospitals would be required to report four calendar quarters of data for a total of nine eCQMs (six specified eCQMs and three self-selected eCQMs).

(b) Proposal To Change the Reporting and Submission Requirements for eCQMs for the CY 2027 Reporting Period/FY 2029 Payment Determination and for Subsequent Years

Beginning with the CY 2027 reporting period/FY 2029 payment determination, we are proposing to modify the eCQM reporting and submission requirements to require hospitals to report on the following two eCQMs in addition to the eCQMs proposed for the CY 2026 reporting period/FY 2028 payment determination: (1) Hospital Harm—Pressure Injury eCQM; and (2) Hospital Harm—Acute Kidney Injury eCQM. If this proposal is finalized, beginning with the CY 2027 reporting period/FY 2029 payment determination, hospitals would be required to report four calendar quarters of data for a total of

[459] AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. Available at: *https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html.*

[460] President's Council of Advisors on Science and Technology. (2023). Report to the President: A Transformational Effort on Patient Safety. Available at: *https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST_Patient-Safety-Report_Sept2023.pdf.*

[461] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

[462] Centers for Medicare & Medicaid Services. (2023). CMS National Quality Strategy. Available at: *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*

eleven eCQMs (eight specified eCQMs and three self-selected eCQMs).

This stepwise approach to increasing the number of required eCQMs is in response to public comments noting the burden and resources necessary to implement new eCQMs (88 FR 59145 through 59149, and 88 FR 59149 through 59154), while also balancing the need to prioritize more comprehensive reporting on important safety and preventable harm metrics. Waiting until the CY 2027 reporting period/FY 2029 payment determination to require that hospitals report on these two Hospital Harm eCQMs would allow hospitals to experience2 years of self-selecting to report on these relatively new eCQMs and build the infrastructure necessary to report these measures (88 FR 59145 through 59149, and 88 FR 59149 through 59154). Therefore, we are proposing to require these two measures in the CY 2027 reporting period instead of the CY 2026 reporting period to provide hospitals with additional time to gain experience with these newer measures.

(c) Summary of Proposed Changes to the eCQM Reporting and Submission Requirements

We refer readers to section IIX.C.8. for the full list of eCQMs by payment determination in the Hospital IQR Program. If a hospital does not have patients that meet the denominator criteria for any of the eCQMs included in this proposal, the hospital would submit a zero denominator declaration for the measure that allows a hospital to meet the reporting requirements for a particular eCQM. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. A QRDA Category I file with patients meeting the initial patient population of the applicable measures, a zero denominator declaration, and/or a case threshold exemption all count toward a successful submission for eCQMs for the Hospital IQR Program (82 FR 38387). The following Table IX.C.9 summarizes our proposed policies:

TABLE IX.C.9. CURRENT AND PROPOSED eCQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2024 REPORTING PERIOD/FY 2026 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period/ Payment Determination	Total Number of eCQMs Reported	eCQMs Required to be Reported
CY 2024/FY 2026 and CY 2025/FY 2027 (87 FR 49299 through 49302)	Six	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM
Proposed: CY 2026/FY 2028	Nine	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM; and • Hospital Harm - Severe Hyperglycemia eCQM; and • Hospital Harm - Severe Hypoglycemia eCQM; and • Hospital Harm - Opioid-Related Adverse Events eCQM
Proposed: CY 2027/FY 2029 (and for subsequent years)	Eleven	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM; and • Hospital Harm - Severe Hyperglycemia eCQM; and • Hospital Harm - Severe Hypoglycemia eCQM; and • Hospital Harm - Opioid-Related Adverse Events eCQM; and • Hospital Harm - Pressure Injury eCQM; and • Hospital Harm - Acute Kidney Injury eCQM

We invite public comment on our proposal to increase the number of mandatory eCQMs over a two-year period to ultimately require reporting on five additional eCQMs beginning with CY 2026 Reporting Period/FY 2028 Payment Determination. We refer readers to section IX.F.6.b. of this proposed rule, in which we propose the same reporting and submission requirements under the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals.

10. Validation of Hospital IQR Program Data

We are proposing changes to our policies for eCQM validation scoring processes beginning with validation of eCQMs affecting the FY 2028 payment determinations.

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), we finalized several requirements for the validation of eCQM data, including a policy requiring submission of at least 75 percent of sampled eCQM medical records in a timely and complete manner for validation (81 FR 57181). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58950 through 58952), we finalized the existing Hospital IQR Program validation scoring processes such that a combined score is calculated based on a weighted combination of a hospital's

validation performance for chart-abstracted measures and eCQMs. Under the aligned validation policies, each hospital selected for validation is expected to submit medical record data for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). Beginning with validation procedures affecting the FY 2024 payment determination, we finalized a policy to annually identify one pool of up to 200 hospitals selected through random selection and one pool of up to 200 hospitals selected using targeting criteria to participate in both chart-abstracted measure and eCQM validation (85 FR 58942 through 58953).

We refer readers to 42 CFR 412.140(d) for our codification of validation policies and to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49308 through 49310) for a discussion of the most recent changes to chart-abstracted and eCQM data validation requirements for the Hospital IQR Program wherein we finalized the requirement that hospitals selected for validation must submit timely and complete data for 100 percent of requested records for eCQM validation. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178 through 57180) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

b. Proposal To Modify eCQM Data Validation Beginning With the CY 2025 Reporting Period/FY 2028 Payment Determination

(1) Proposal To Modify eCQM Validation Scoring Beginning With CY 2025 eCQM Data Affecting the FY 2028 Payment Determination

Under the existing eCQM data validation policy, as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181), the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) has not affected a hospital's validation score. Instead, hospitals have been scored on the completeness of eCQM medical record data that were submitted for the validation process. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38401), we noted our intention for the accuracy of eCQM data validation to affect validation scores in the future.

We have assessed agreement rates, or the rates by which hospitals' reported eCQM data agree with the data resulting from the review process that we conduct as part of validation. The agreement rates for validation accuracy, which have been confidentially reported to hospitals selected for eCQM validation in recent years, are consistently robust overall. For example, around 90 percent (national average agreement rate) for current eCQMs that would be validated in FY 2028 (ranging from a low average of about 84 percent for the Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM) to a high of average of about 94 percent for the Antithrombotic Therapy by the End of Hospital Day Two eCQM), based on FY 2024 validation results. With the low end of the average accuracy range being well above a passing threshold of 75 percent, it is now appropriate to move forward with scoring hospitals' eCQM data based on the accuracy of the data submitted for purposes of determining whether a hospital has met the validation requirements under the Hospital IQR Program. Therefore, in this proposed rule, we are proposing to implement eCQM validation scoring based on the accuracy of eCQM data beginning with CY 2025 eCQM data affecting the FY 2028 payment determination. By the time our proposed eCQM validation scoring methodology would go into effect, we will have been validating eCQM data for completeness for 8 years, which is ample time for hospitals to have prepared for data to be validated based on its accuracy. We would also note that because hospitals are already required to submit 100 percent of requested eCQM medical records to pass the eCQM validation requirement, there is no additional burden to hospitals associated with this proposal to begin scoring the submitted records.

Separately, we are proposing to remove the requirement at § 412.140(d)(2)(ii) that hospitals submit 100 percent of the requested eCQM medical records to pass the eCQM validation requirement and proposing that missing eCQM medical records would be treated as mismatches, beginning with the validation of CY 2025 eCQM data affecting the FY 2028 payment determination. This is the same methodology that is applied for missing medical records in chart-abstracted measure validation to incentivize the timely submission of requested medical records. Because mismatches count against the agreement rate, by treating missing eCQM medical records as mismatches, we can ensure our validation scoring methodology clearly requires that hospitals submit all necessary eCQM data for our review without also requiring medical records submissions.

We are proposing that eCQM validation scores be determined using the same methodology that is currently used to score chart-abstracted measure validation. Hospitals' eCQM data would be used to compute an agreement rate and its associated confidence interval. The upper bound of the two-tailed 90 percent confidence interval would be used as the final eCQM validation score for the selected hospital. A minimum score of 75 percent accuracy would be required for the hospital to pass the eCQM validation requirement. Based on the FY 2024 results, most measures had national agreement rates well above the proposed 75 percent threshold, however these FY 2024 results are based on only two quarters of data and included data only from eCQMs that have been in the Hospital IQR Program for several years. We anticipate that the average agreement rates may decrease with a full year of data and the introduction of newer eCQMs that hospitals may have less experience reporting. As such, while we may consider raising the minimum passing threshold from 75 percent in future years, at this time we have determined that the 75 percent threshold is appropriate for initial scoring of eCQMs in Hospital IQR Program validation.

We invite public comment on our proposal to Modify eCQM Validation Scoring beginning with CY 2025 eCQM data affecting the FY 2028 payment determination.

(2) Proposal To Modify the Combined Validation Scoring Process Beginning With CY 2025 Data Affecting the FY 2028 Payment Determination

We are proposing to remove the existing combined validation score based on a weighted combination of a hospital's validation performance for chart-abstracted measures and eCQMs and replace it with two separate validation scores, one for chart-abstracted measures, and one for eCQMs. Based on our current policies, the eCQM portion of the combined agreement rate is multiplied by zero percent, and the chart-abstracted measure agreement rate is weighted at 100 percent. A minimum passing score for this combined score is set at 75 percent.

Reporting requirements and procedures for eCQMs are different than those for chart-abstracted measures. For instance, hospitals implement electronic algorithms to query eCQM data and submit eCQM measure results using a custom file layout for quality data reporting to CMS. In contrast, validation of chart-abstracted measures is conducted using measure specifications written to support manual abstraction processes. As such, separate validation scores are consistent with the distinct requirements and procedures for the

reporting of quality measure data. Moreover, CMS intends to retain an emphasis on data accuracy through the validation efforts across both measure types (that is, chart-abstracted measures and eCQMs). It is important to ensure necessary analysis and resources are placed on chart-abstracted measures that are still currently being validated, especially because of their use within the Hospital Value-Based Purchasing (VBP) Program. Therefore, we are proposing to implement two separate scoring processes, one for chart-abstracted measures and one for eCQMs, for the FY 2028 payment determination and subsequent years. Hospitals would be required to receive passing validation scores for both chart-abstracted measure data and eCQM data to pass validation.

Under our proposal, beginning with the validation of CY 2025 data affecting the FY 2028 payment determination, hospitals would receive separate validation scores for both chart-abstracted measure data and eCQM data, which would be used to determine a hospital's overall annual payment update. As established in the FY 2006 IPPS final rule (70 FR 47420 through 47428), a hospital that fails to meet validation requirements may not receive the full annual payment update. Under our proposal, if a hospital fails either chart-abstracted validation requirements or eCQM validation requirements, it may not receive the full annual payment update. To be eligible for a full annual payment update, provided all other Hospital IQR Program requirements are met, a hospital would have to attain at least a 75 percent validation score for chart-abstracted measure validation and at least a 75 percent validation score for eCQM data validation.

Our existing and newly proposed validation scoring changes are summarized in Table IX.C.10.

TABLE IX.C.10. SUMMARY OF CURRENT AND PROPOSED VALIDATION SCORING POLICIES

Validation Process Description	Quarters of Data Required for Validation	Scoring
Current Validation Scoring for the FY 2025 – FY 2027 Payment Determinations (87 FR 49308 through 49310)		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2022 – 4Q 2022	Chart-Abstracted Measures: at least 75% validation score (weighted at 100%) And eCQMs: Successful submission of 100% of requested medical records
Proposed Update to eCQM Validation Scoring for the FY 2028 Payment Determination and Subsequent Years		
Up to 200 Random Hospitals + up to 200 Targeted Hospitals selected for both Chart-Abstracted Measures and eCQM Validation	1Q 2025 – 4Q 2025	Chart-Abstracted Measures: at least 75% validation score And eCQMs: at least 75% validation score

We invite public comment on our proposal to Modify the Combined Validation Scoring Process beginning with CY 2025 Data affecting the FY 2028 payment determination.

11. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We are not proposing any changes to this policy in this proposed rule. We refer readers to the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites) for more details on DACA requirements.

12. Public Display Requirements

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare,* or its successor website, after a 30-day preview period (78 FR 50776 through 50778).

We are not proposing any changes to these policies or the public reporting of eCQM data or overall hospital star ratings in this proposed rule. We also refer readers to the QualityNet website at: *https://qualitynet.cms.gov/inpatient/public-reporting* (or other successor CMS designated websites) for details on public display requirements.

13. Reconsideration and Appeal Procedures

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e), we established an approach for reconsideration and appeal procedures for the Hospital IQR Program. As part of this reconsideration process, hospitals can request reconsideration if CMS determines that the hospital did not meet the Hospital IQR Program's validation requirements. Under these requirements as established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50225 through 50229), for purposes of validation, hospitals are required to resubmit copies of all medical records that were originally submitted to the Clinical Data Abstraction Center (CDAC) each relevant quarter. With the transition to all electronic submission of copies of medical records for Hospital IQR Program validation as established in they FY 2021 IPPS/LTCH final rule (85 FR 58949 through 58950), both through eCQMs and digitized charts, the current reconsideration requirement to resubmit records used for validation results is no longer necessary and creates duplicative files and work.

Therefore, we are proposing to revise § 412.140(e)(2)(vii)(A) to no longer require hospitals to resubmit medical records as part of their request for reconsideration of validation, beginning with CY 2023 discharges affecting the FY 2026 payment determination.

Under our proposal, hospitals that need to submit a revised medical record may still do so, but those hospitals that would otherwise be resubmitting copies of the previously submitted records would no longer be required to submit them. Removing record submission as a requirement for validation reconsideration would reduce hospital administrative burden for the majority of hospitals that do not have revised records to submit. Making this step optional would also reduce the burden for CMS to collect and track medical records that are already available.

We invite public comment on our proposal to remove the requirement for hospitals to resubmit medical records as part of their request for reconsideration of validation, beginning with CY 2023 discharges affecting the FY 2026 payment determination.

14. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We are not proposing any changes to this policy in this proposed rule. We refer readers to § 412.140(c)(2) and the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites) for our current requirements for submission of a request for an exception.

D. Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, authorized by section 1866(k) of the Act, applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). In this proposed rule, we are proposing to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year. We are also proposing to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure and to move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure.[463]

2. Proposal To Adopt the Patient Safety Structural Measure Beginning With the CY 2025 Reporting Period/FY 2027 Program Year

We refer readers to section IX.B.1. of the preamble of this proposed rule where we are proposing adoption of the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year for the PCHQR Program. We are also proposing to adopt this measure for the Hospital Inpatient Quality Reporting (IQR) Program, as discussed in that section.

3. Proposal To Modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure Beginning With the CY 2025 Reporting Period/FY 2027 Program Year

We refer readers to section IX.B.2. of the preamble of this proposed rule where we are proposing to modify the HCAHPS Survey measure (CBE #0166) beginning with the CY 2025 reporting period/FY 2027 program year. We are also proposing to adopt the same modifications to this measure for purposes of the Hospital IQR Program and the Hospital VBP Program, as discussed in the same section.

4. Summary of Previously Adopted and Newly Proposed PCHQR Program Measures for the CY 2025 Reporting Period/FY 2027 Program Year and Subsequent Years

Table IX.D.–01 summarizes the previously adopted and the newly proposed measures for the PCHQR Program measure set beginning with the CY 2025 reporting period/FY 2027 program year.

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[463] To provide clarity and to better align with the Hospital IQR Program, we are changing the name of the Facility Commitment to Health Equity measure in the PCHQR Program to the Hospital Commitment to Health Equity measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.

TABLE IX.D.-01: PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED MEASURES FOR THE PCHQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2025 REPORTING PERIOD/FY 2027 PROGRAM YEAR

Short Name	CBE Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
Flu HCP Vaccination	0431	Influenza Vaccination Coverage Among Healthcare Personnel (HCP)
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery)
MRSA	1716	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
N/A	N/A	Patient Safety Structural Measure*
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer - Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer - Not Admitted to Hospice
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer - Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer - Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey
N/A	N/A	Documentation of Goals of Care Discussions Among Cancer Patients
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer
Health Equity Measures		
HCHE	N/A	Hospital Commitment to Health Equity
N/A	N/A	Screening for Social Drivers of Health
N/A	N/A	Screen Positive Rate for Social Drivers of Health

* Indicates new measure proposed in this proposed rule.

5. Proposal To Move Up the Start Date for Public Display of the Hospital Commitment to Health Equity Measure

In the FY 2024 IPPS/LTCH PPS final rule, we adopted the Hospital Commitment to Health Equity measure for the PCHQR measure set beginning with the CY 2024 reporting period/FY 2026 program year (88 FR 59204 through 59210). We also finalized that we would publicly report PCH performance on this measure beginning with CY 2024 data beginning July 2026 or as soon as feasible thereafter (88 FR 59209; 59228).

In this proposed rule, we are proposing to accelerate the timeline for beginning to publicly report PCH performance on this measure. Specifically, we are proposing to start public reporting of PCH performance on this measure using CY 2024 data beginning January 2026 or as soon as feasible thereafter. We believe that the public could benefit from having access to the information sooner because the data provide an opportunity to recognize PCHs that have attested to their commitment to health equity at an earlier date. We also believe the modification of the date for public reporting would promote efficiencies through alignment of the performance periods, data submission periods, and the anticipated public reporting release with the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program that adopted the Facility Commitment to Health Equity measure (which requires the same attestations as the Hospital Commitment to Health Equity measure) beginning with reporting of CY 2024 data for the FY 2026 payment determination and would provide this information for providers participating in the PCHQR Program and the IPFQR Program types simultaneously. We are seeking comment on this proposal to move up the start of public reporting of the Hospital Commitment to Health

Equity measure to January 2026 or as soon as feasible thereafter.

6. Summary of Previously Finalized Public Display Policies and Proposed Public Display Start Date Change for the PCHQR Program

Our previously finalized public display policies and newly proposed public display start date change for the Hospital Commitment to Health Equity measure for the PCHQR Program are described in Table IX.D.–02:

TABLE IX.D.-02: PREVIOUSLY FINALIZED PUBLIC DISPLAY POLICIES AND NEWLY PROPOSED PUBLIC DISPLAY CHANGE FOR THE PCHQR PROGRAM

Measures	Public Display Dates
• HCAHPS (CBE #0166)	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (CBE #0753) • NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (CBE #1716) • NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (CBE #1717) • NHSN Influenza Vaccination Coverage Among Healthcare Personnel (CBE #0431)	2019 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• COVID-19 Vaccination Coverage Among Healthcare Personnel	October 2022 and subsequent years
• CAUTI (CBE #0138) • CLABSI (CBE #0139)	October 2022 and subsequent years
• 30-day Unplanned Readmissions for Cancer Patients (CBE #3188)	October 2023 and subsequent years
• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (CBE #0210) • Proportion of Patients Who Died from Cancer Not Admitted to Hospice (CBE #0215) • Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (CBE #0213) • Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (CBE #0216)	July 2024 or as soon as feasible thereafter
• Surgical Treatment Complications for Localized Prostate Cancer Measure (PCH-37)	July 2024 or as soon as feasible thereafter
• Hospital Commitment to Health Equity*	January 2026 or as soon as feasible thereafter
• Documentation of Goals of Care Discussions Among Cancer Patients	July 2026 or as soon as feasible thereafter
• Screening for Social Drivers of Health	July 2027 or as soon as feasible thereafter
• Screen Positive Rate for Social Drivers of Health	July 2027 or as soon as feasible thereafter

* Proposed new start date for publicly displaying this measure.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the

LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard federal rate for discharges for an LTCH during a fiscal year (FY) if the LTCH has not complied with the LTCH QRP requirements specified for that FY. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the LTCH QRP. We have codified our program requirements in our regulations at 42 CFR 412.560.

We are proposing to require LTCHs to report four new items to the LTCH Continuity Assessment and Record of Evaluation (CARE) Data Set (LCDS) and modify one item on the LCDS as described in section IX.E.4. of the preamble of this proposed rule. Second, we are proposing to extend the Admission assessment window for the LCDS. Third, we are seeking information on future measure concepts for the LTCH QRP. Finally, we are seeking information on a future LTCH Star Rating system.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations, we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2025 LTCH QRP

The LTCH QRP currently has 18 adopted measures, which are set out in Table IX.E.–01. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

TABLE IX.E.-01. QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient	Transfer of Health Information to the Patient Post-Acute Care (PAC)
DC Function	Discharge Function Score
Patient/Resident COVID-19 Vaccine	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

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We are not proposing to adopt any new measures for the LTCH QRP.

4. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements and Modify One Item Collected as a Standardized Patient Assessment Data Element Beginning With the FY 2028 LTCH QRP

In this proposed rule, we are proposing to add four new items [464] to be collected as standardized patient assessment data elements under the social determinants of health (SDOH) category under the LTCH QRP: Living Situation (one item); Food (two items); and Utilities (one item). We are also proposing to modify one of the current items collected as standardized patient assessment data under the SDOH category (the Transportation item), as described in section X.E.4.e. of the preamble of this proposed rule.

a. Definition of Standardized Patient Assessment Data

Section 1886(m)(5)(F)(ii) of the Act requires LTCHs to submit standardized patient assessment data required under section 1899B(b)(1) of the Act. Section 1899B(b)(1)(A) of the Act requires post-acute care (PAC) providers to submit standardized patient assessment data under applicable reporting provisions (which, for LTCHs, is the LTCH QRP) with respect to the admission and discharge of an individual (and more frequently as the Secretary deems appropriate). Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the PAC assessment instruments in order for PAC providers, including LTCHs, to submit standardized patient assessment data under the Medicare program. LTCHs are currently required to report patient assessment data through the LCDS. Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is with respect to the following categories: (1) functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

b. Social Determinants of Health Collected as Standardized Patient Assessment Data Elements

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect standardized patient assessment data elements with respect to other categories deemed necessary and appropriate. Accordingly, we finalized the creation of the SDOH category of standardized patient assessment data elements in the FY 2020 LTCH PPS final rule (84 FR 42578 through 42581), and defined SDOH as the socioeconomic, cultural, and environmental circumstances in which individuals live that impact their health.[465] According to the World Health Organization, research shows that the SDOH can be more important than health care or lifestyle choices in influencing health, accounting for between 30–55% of health outcomes.[466] This is a part of a growing body of research that highlights the importance of SDOH on health outcomes. Subsequent to the FY 2020 LTCH PPS final rule, we expanded our definition of SDOH: SDOH are the conditions in the environments where people are born, live, learn, work, play, worship and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[467] [468] [469] This expanded definition aligns our definition of SDOH with the definition used by HHS agencies, including OASH, the Centers for Disease Control and Prevention (CDC) and the White House Office of Science and Technology Policy.[470] [471] We currently collect seven items in this SDOH category of standardized patient assessment data elements: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 42578 through 42581).

We currently collect seven SDOH items in the category of standardized patient assessment data elements: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 42577 through 42579).[472] In accordance with our authority under section 1899B(b)(1)(B)(vi) of the Act, we similarly finalized the creation of the SDOH category of standardized patient assessment data elements for Skilled Nursing Facilities (SNFs) in the FY 2020 SNF PPS final rule (84 FR 38805 through 38817), for Inpatient Rehabilitation Facilities (IRFs) in the FY 2020 IRF PPS final rule (84 FR 39149 through 39161), and for Home Health Agencies (HHAs) in the Calendar Year (CY) 2020 HH PPS final rule (84 60597 through 60608). We also collect the same seven SDOH items in these PAC providers' respective patient/resident assessment instruments (84 FR 38817, 39161, and 60610, respectively).

Access to standardized data relating to SDOH on a national level permits us to conduct periodic analyses, and to assess their appropriateness as risk adjustors or in future quality measures. Our ability to perform these analyses and to make adjustments relies on existing data collection of SDOH items from PAC settings. We adopted these SDOH items using common standards and definitions across the four PAC providers to promote interoperable exchange of longitudinal information among these PAC providers, including LTCHs, and other providers. We believe this information may facilitate coordinated care, improve patient focused care planning, and allow for continuity of the discharge planning process from PAC settings.

We noted in our FY 2020 LTCH PPS final rule that each of the items was identified in the 2016 National Academies of Sciences, Engineering,

[464] Items may also be referred to as ''data elements.''

[465] Office of the Assistant Secretary for Planning and Evaluation (ASPE). Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 28, 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[466] World Health Organization. Social determinants of health. Available at: *https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.*

[467] Using Z Codes: The Social Determinants of Health (SDOH). Data Journey to Better Outcomes.

[468] Improving the Collection of Social Determinants of Health (SDOH) Data with ICD–10–CM Z Codes. *https://www.cms.gov/files/document/cms-2023-omh-z-code-resource.pdf.*

[469] CMS.gov. Measures Management System (MMS). CMS Focus on Health Equity. Health Equity Terminology and Quality Measures. *https://mmshub.cms.gov/about-quality/quality-at-CMS/goals/cms-focus-on-health-equity/health-equity-terminology.*

[470] Centers for Disease Control and Prevention. Social Determinants of Health (SDOH) and PLACES Data.

[471] ''U.S. Playbook To Address Social Determinants Of Health'' from the White House Office Of Science And Technology Policy (November 2023).

[472] These SDOH data are also collected for purposes outlined in section 2(d)(2)(B) of the Improving Medicare Post-Acute Care Transitions Act (IMPACT Act). For a detailed discussion on SDOH data collection under section 2(d)(2)(B) of the IMPACT Act, see the FY 2020 LTCH PPS final rule (84 FR 42577 through 42579).

and Medicine (NASEM) report as impacting care use, cost, and outcomes for Medicare beneficiaries (84 FR 39150). At that time, we acknowledged that other items may also be useful to understand. The SDOH items we are proposing to collect as standardized patient assessment data elements under the SDOH category in this proposed rule were also identified in the 2016 NASEM report [473] or the 2020 NASEM report [474] as impacting care use, cost, and outcomes for Medicare beneficiaries. These items have the potential to affect treatment preferences and goals of patients and their caregivers. Identification of these SDOH items may also help LTCHs be in a position to offer assistance, by connecting patients and their caregivers with these associated needs to social support programs, as well as inform our understanding of patient complexity.

Health-related social needs (HRSNs) are the resulting effects of SDOH, which are individual-level, adverse social conditions that negatively impact a person's health or health care.[475] Examples of HRSNs include lack of access to food, housing, or transportation, and have been associated with poorer health outcomes, greater use of emergency departments and hospitals, and higher health care costs. Certain HRSNs can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[476] This is particularly true for food security, housing stability, utilities security, and access to transportation.[477]

We are proposing to require LTCHs collect and submit four new items in the LCDS as standardized patient assessment data elements under the SDOH category because these items would collect information not already captured by the current SDOH items. Specifically, we believe the ongoing identification of SDOH would have three significant benefits. First, promoting screening for SDOH could serve as evidence-based building blocks for supporting healthcare providers in actualizing their commitment to address disparities that disproportionately impact underserved communities. Second, screening for SDOH improves health equity through identifying potential social needs so the LTCH may address those with the patient, their caregivers, and community partners during the discharge planning process, if indicated.[478] Third, these SDOH items could support our ongoing LTCH QRP initiatives by providing data with which to stratify LTCHs' performance on measures or in future quality measures.

Additional collection of SDOH items would permit us to continue developing the statistical tools necessary to maximize the value of Medicare data and improve the quality of care for all beneficiaries. For example, we recently developed and released the Health Equity Confidential Feedback Reports, which provided data to LTCHs on whether differences in quality measure outcomes are present for their patients by dual-enrollment status and race and ethnicity.[479] We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars [480] and a Biden-Harris Administration priority.[481]

c. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements Beginning With the FY 2028 LTCH QRP

We are proposing to require LTCHs collect four new items as standardized patient assessment data elements under the SDOH category using the LCDS: one item for Living Situation, as described in section IX.4.c.(1) of this proposed rule; two items for Food, as described in section IX.4.c.(2) of this proposed rule; and one item for Utilities, as described in section IX.4.c.(3) of this proposed rule.

We selected the proposed SDOH items from the AHC HRSN Screening Tool developed for the AHC Model. The AHC HRSN Screening Tool is a universal, comprehensive screening for HRSNs that addresses five core domains as follows: (i) housing instability (for example, homelessness, poor housing quality), (ii) food insecurity, (iii) transportation difficulties, (iv) utility assistance needs, and (v) interpersonal safety concerns (for example, intimate-partner violence, elder abuse, child maltreatment).[482]

We believe that requiring LTCHs to report new items that are currently included in the AHC HRSN Screening Tool would further standardize the screening of SDOH across quality programs. For example, our proposal would align, in part, with the requirements of the Hospital Inpatient Quality Reporting (IQR) Program and the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. As of January 2024, hospitals are required to report whether they have screened patients for the standardized SDOH categories of housing stability, food security, utility difficulties, transportation needs, and interpersonal safety to meet the Hospital IQR Program requirements.[483] Beginning January 2025, IPFs will also be required to report whether they have screened patients for the same set of SDOH

[473] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health.* (February 2019).

[474] National Academies of Sciences, Engineering, and Medicine. 2020. Leading Health Indicators 2030: Advancing Health, Equity, and Well-Being. Washington, DC: The National Academies Press. *https://doi.org/10.17226/25682.*

[475] Centers for Medicare & Medicaid Services. ''A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights.'' August 2022. Available at *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[476] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/.*

[477] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/.*

[478] American Hospital Association. (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[479] In October 2023, we released two new annual Health Equity Confidential Feedback Reports to LTCHs: The Discharge to Community (DTC) Health Equity Confidential Feedback Report and the Medicare Spending Per Beneficiary (MSPB) Health Equity Confidential Feedback Report. The PAC Health Equity Confidential Feedback Reports stratified the DTC and MSPB measures by dual-enrollment status and race/ethnicity. For more information on the Health Equity Confidential Feedback Reports, please refer to the Education and Outreach materials available on the LTCH QRP Training web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-quality-reporting-training.*

[480] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go from Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[481] The White House. The Biden-Harris Administration Immediate Priorities [website]. *https://www.whitehouse.gov/priorities/.*

[482] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

[483] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49191 *through* 49194).

categories.[484] As we continue to standardize data collection across PAC settings, we believe using common standards and definitions for new items is important to promote interoperable exchange of longitudinal information between LTCHs and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process.

Below we describe each of the four proposed items in more detail.

(1) Living Situation

Healthy People 2030 prioritizes economic stability as a key SDOH, of which housing stability is a component.[485] [486] Lack of housing stability encompasses several challenges, such as having trouble paying rent, overcrowding, moving frequently, or spending the bulk of household income on housing.[487] These experiences may negatively affect one's physical health and access to health care. Housing instability can also lead to homelessness, which is housing deprivation in its most severe form.[488] On a single night in 2023, roughly 653,100 people, or 20 out of every 10,000 people in the United States, were experiencing homelessness.[489] Studies also found that people who are homeless have an increased risk of premature death and experience chronic disease more often than among the general population.[490]

We believe that LTCHs can use information obtained from the Living Situation item during a patient's discharge planning. For example, LTCHs could work in partnership with community care hubs and community-based organizations to establish new care transition workflows, including referral pathways, contracting mechanisms, data sharing strategies, and implementation training that can track HRSNs to ensure unmet needs, such as housing, are successfully addressed through closed loop referrals and follow-up.[491] LTCHs could also take action to help alleviate a patient's other related costs of living, like food, by referring the patient to community-based organizations that would allow the patient's additional resources to be allocated towards housing without sacrificing other needs.[492] Finally, LTCHs could use the information obtained from the Living Situation item to better coordinate with other healthcare providers, facilities, and agencies during transitions of care, so that referrals to address a patient's housing stability are not lost during vulnerable transition periods.

Due to the potential negative impacts housing instability can have on a patient's health, we are proposing to adopt the Living Situation item as a new standardized patient assessment data element under the SDOH category. This proposed Living Situation item is based on the Living Situation item currently collected in the AHC HRSN Screening Tool,[493] [494] and was adapted from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool.[495] The proposed Living Situation item asks, ''What is your living situation today?'' The proposed response options are: (1) I have a steady place to live; (2) I have a place to live today, but I am worried about losing it in the future; (3) I do not have a steady place to live; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of the proposed Living Situation item to be adopted as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the LCDS and LTCH Manual web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

(2) Food

The U.S. Department of Agriculture, Economic Research Service defines a lack of food security as a household-level economic and social condition of limited or uncertain access to adequate food.[496] Adults who are food insecure may be at an increased risk for a variety of negative health outcomes and health disparities. For example, a study found that food-insecure adults may be at an increased risk for obesity.[497] Another study found that food-insecure adults have a significantly higher probability of death from any cause or cardiovascular disease in long-term follow-up care, in comparison to adults that are food secure.[498]

While having enough food is one of many predictors for health outcomes, a diet low in nutritious foods is also a factor.[499] The United States Department of Agriculture (USDA) defines nutrition security as ''consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being.'' [500] Nutrition security builds on

[484] Centers for Medicare & Medicaid Services, FY2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[485] *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[486] Healthy People 2030 is a long-term, evidence-based effort led by the U.S. Department of Health and Human Services (HHS) that aims to identify nationwide health improvement priorities and improve the health of all Americans.

[487] Kushel, M.B., Gupta, R., Gee, L., & Haas, J.S. (2006). Housing instability and food insecurity as barriers to health care among low-income Americans. *Journal of General Internal Medicine, 21*(1), 71–77. doi: 10.1111/j.1525–1497.2005.00278.x.

[488] Homelessness is defined as ''lacking a regular nighttime residence or having a primary nighttime residence that is a temporary shelter or other place not designed for sleeping.'' Crowley, S. (2003). The affordable housing crisis: Residential mobility of poor families and school mobility of poor children. Journal of Negro Education, *72*(1), 22–38. doi: 10.2307/3211288.

[489] The 2023 Annual Homeless Assessment Report (AHAR) to Congress. The U.S. Department of Housing and Urban Development 2023. *https://www.huduser.gov/portal/sites/default/files/pdf/2023-AHAR-Part-1.pdf.*

[490] Baggett, T.P., Hwang, S.W., O'Connell, J.J., Porneala, B.C., Stringfellow, E.J., Orav, E.J., Singer, D.E., & Rigotti, N.A. (2013). Mortality among homeless adults in Boston: Shifts in causes of death over a 15-year period. JAMA Internal Medicine, 173(3), 189–195. doi: 10.1001/jamainternmed.2013.1604. Schanzer, B., Dominguez, B., Shrout, P.E., & Caton, C.L. (2007). Homelessness, health status, and health care use. American Journal of Public Health, 97(3), 464–469. doi: 10.2105/AJPH.2005.076190.

[491] U.S. Department of Health & Human Services (HHS), Call to Action, ''Addressing Health Related Social Needs in Communities Across the Nation.'' November 2023. *https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf.*

[492] Henderson, K.A., Manian, N., Rog, D.J., Robison, E., Jorge, E., AlAbdulmunem, M. ''Addressing Homelessness Among Older Adults'' (Final Report). Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. October 26, 2023.

[493] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

[494] The AHC HRSN Screening Tool Living Situation item includes two questions. In an effort to limit IRF burden, we are only proposing the first question.

[495] National Association of Community Health Centers and Partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. ''PRAPARE.'' 2017. *https://prapare.org/the-prapare-screening-tool/.*

[496] U.S. Department of Agriculture, Economic Research Service. (n.d.). *Definitions of food security.* Retrieved March 10, 2022, from *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/definitions-of-food-security/*

[497] Hernandez, D.C., Reesor, L.M., & Murillo, R. (2017). Food insecurity and adult overweight/obesity: Gender and race/ethnic disparities. *Appetite, 117,* 373–378.

[498] Banerjee, S., Radak, T., Khubchandani, J., & Dunn, P. (2021). Food Insecurity and Mortality in American Adults: Results From the NHANES-Linked Mortality Study. Health promotion practice, 22(2), 204–214. *https://doi.org/10.1177/1524839920945927.*

[499] National Center for Health Statistics. (2022, September 6). Exercise or Physical Activity. Retrieved from Centers for Disease Control and Prevention: *https://www.cdc.gov/nchs/fastats/exercise.htm.*

[500] Food and Nutrition Security. (n.d.). USDA. *https://www.usda.gov/nutrition-security.*

and complements long standing efforts to advance food security.[501] Studies have shown that older adults struggling with food security consume fewer calories and nutrients and have lower overall dietary quality than those who are food secure, which can put them at nutritional risk.[502] Older adults are also at a higher risk of developing malnutrition, which is considered a state of deficit, excess, or imbalance in protein, energy, or other nutrients that adversely impacts an individual's own body form, function, and clinical outcomes.[503] About 50% of older adults are affected by malnutrition, which is further aggravated by a lack of food security and poverty.[504] These facts highlight why the Biden-Harris Administration launched the White House Challenge to End Hunger and Build Health Communities.[505]

We believe that adopting items to collect and analyze information about a patient's food security at home could provide additional insight to their health complexity and help facilitate coordination with other healthcare providers, facilities, and agencies during transitions of care, so that referrals to address a patient's food security are not lost during vulnerable transition periods. For example, an LTCH's dietitian or other clinically qualified nutrition professional could work with the patient and their caregiver to plan healthy, affordable food choices prior to discharge.[506] LTCHs could also refer a patient that indicates lack of food security to government initiatives such as the Supplemental Nutrition Assistance Program (SNAP) and food pharmacies (programs to increase access to healthful foods by making them affordable), two initiatives that have been associated with lower health care costs and reduced hospitalization and emergency department visits.[507]

We are proposing to adopt two Food items as new standardized patient assessment data elements under the SDOH category. These proposed items are based on the Food items currently collected in the AHC HRSN Screening Tool, and were adapted from the USDA 18-item Household Food Security Survey (HFSS).[508] The first proposed Food item states, ''Within the past 12 months, you worried that your food would run out before you got money to buy more.'' [509] The second proposed Food item states, ''Within the past 12 months, the food you bought just didn't last and you didn't have money to get more. We propose the same response options for both items: (1) Often true; (2) Sometimes true; (3) Never True; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of the proposed Food items to be adopted as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the LCDS and LTCH Manual web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

(3) Utilities

A lack of energy (utility) security can be defined as an inability to adequately meet basic household energy needs.[510] According to the Department of Energy, one in three households in the U.S. are unable to adequately meet basic household energy needs.[511] The consequences associated with a lack of utility security are represented by three primary dimensions: economic, physical, and behavioral. Patients with low incomes are disproportionately affected by high energy costs, and they may be forced to prioritize paying for housing and food over utilities.[512] Some patients may face limited housing options and therefore are at increased risk of living in lower-quality physical conditions with malfunctioning heating and cooling systems, poor lighting, and outdated plumbing and electrical systems.[513] Patients with a lack of utility security may use negative behavioral approaches to cope, such as using stoves and space heaters for heat.[514] In addition, data from the Department of Energy's U.S. Energy Information Administration confirm that a lack of energy security disproportionately affects certain populations, such as low-income and African American households.[515] The effects of a lack of utility security include vulnerability to environmental exposures such as dampness, mold, and thermal discomfort in the home, which have a direct impact on a person's health.[516] [517] For example, research has shown associations between a lack of energy security and respiratory conditions as well as mental health-related disparities and poor sleep quality in vulnerable populations such as the elderly, children, the socioeconomically disadvantaged, and the medically vulnerable.[518]

[501] Food and Nutrition Service. (March 2022). USDA. *https://www.usda.gov/sites/default/files/documents/usda-actions-nutrition-security.pdf.*

[502] Ziliak, J.P., & Gundersen, C. (2019). The State of Senior Hunger in America 2017: An Annual Report. Prepared for Feeding America. Available at: *https://www.feedingamerica.org/research/senior-hunger-research/senior.*

[503] The Malnutrition Quality Collaborative. (2020). National Blueprint: Achieving Quality Malnutrition Care for Older Adults, 2020 Update. Washington, DC: Avalere Health and Defeat Malnutrition Today. Available at: *https://defeatmalnutrition.today/advocacy/blueprint/.*

[504] Food Research & Action Center (FRAC). ''Hunger is a Health Issue for Older Adults: Food Security, Health, and the Federal Nutrition Programs.'' December 2019. *https://frac.org/wp-content/uploads/hunger-is-a-health-issue-for-older-adults-1.pdf.*

[505] The White House Challenge to End Hunger and Build Health Communities (Challenge) was a nationwide call-to-action released on March 24, 2023 to stakeholders across all of society to make commitments to advance President Biden's goal to end hunger and reduce diet-related diseases by 2030—all while reducing disparities. More information on the White House Challenge to End Hunger and Build Health Communities can be found: *https://www.whitehouse.gov/briefing-room/statements-releases/2023/03/24/fact-sheet-biden-harris-administration-launches-the-white-house-challenge-to-end-hunger-and-build-healthy-communities-announces-new-public-private-sector-actions-to-continue-momentum-from-hist/.*

[506] Schroeder K., Smaldone A., Food Insecurity: A Concept Analysis. Nurse Forum. 2015 Oct.–Dec.;50(4):274–84. doi: 10.1111/nuf.12118. Epub. 2015 Jan. 21. PMID: 25612146; PMCID: PMC4510041.

[507] Tsega M., Lewis C., McCarthy D., Shah T., Coutts K., Review of Evidence for Health-Related Social Needs Interventions. July 2019. The Commonwealth Fund. *https://www.commwealthfund.org/sites/default/files/2019-07/ROI-EVIDENCE-REVIEW-FINAL-VERSION.pdf.*

[508] More information about the HFSS tool can be found at *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/survey-tools/.*

[509] The AHC HRSN Screening Tool Food item includes two questions. In an effort to limit LTCH burden, we are only proposing the first question.

[510] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc. Sci. Med. 2016 Oct.; 167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub. 2016 Aug. 21. PMID: 27592003; PMCID: PMC5114037.

[511] US Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

[512] Hernández D. ''Understanding 'energy insecurity' and why it matters to health.'' Soc. Sci. Med. 2016; 167:1–10.

[513] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc. Sci. Med. 2016 Oct;167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub. 2016 Aug. 21. PMID: 27592003; PMCID: PMC5114037.

[514] Hernández D. ''What 'Merle' Taught Me About Energy Insecurity and Health.'' Health Affairs, VOL.37, NO.3: Advancing Health Equity Narrative Matters. March 2018. *https://doi.org/10.1377/hlthaff.2017.1413.*

[515] US Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

[516] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc. Sci. Med. 2016 Oct.;167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub. 2016 Aug. 21. PMID: 27592003; PMCID: PMC5114037.

[517] Institute of Medicine. (2004). Damp Indoor Spaces and Health. Washington, DC: National Academies Press. *http://www.nap.edu/openbook.php?record_id=11011&page=R2.*

[518] Siegal et al., ''Energy Insecurity Indicators Associated with Increased Odds of Respiratory, Mental Health, And Cardiovascular Conditions.'' Health Affairs 43, NO. 2 (2024): 260–268. *https://doi.org/10.1377/hlthaff.2023.01052.*

We believe adopting an item to collect information about a patient's utility security upon admission to an LTCH would facilitate the identification of patients who may not have utility security and who may benefit from engagement efforts. For example, LTCHs may be able to use the information on utility security to help connect identified patients in need, such as older adults, to programs that can help pay for home energy (heating/cooling) costs, like the Low-Income Home Energy Assistance Program (LIHEAP). LTCHs may also be able to partner with community care hubs and community-based organizations to assist the patient in applying for these and other local utility assistance programs, as well as helping them navigate the enrollment process.[519]

We are proposing to adopt a new item, Utilities, as a new standardized patient assessment data element under the SDOH category. This proposed item is based on the Utilities item currently collected in the AHC HRSN Screening Tool and was adapted from the Children's Sentinel Nutrition Assessment Program (C–SNAP) survey.[520] The proposed Utilities item asks, ''In the past 12 months, has the electric, gas, oil, or water company threatened to shut off services in your home?'' The proposed response options are: (1) Yes; (2) No; (3) Already shut off; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of the proposed Utilities item to be adopted as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the LCDS and LTCH Manual web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

d. Stakeholder Input

We developed our proposal to add these items after considering feedback we received in response to our request for information (RFI) on Closing the Health Equity Gap in CMS Hospital Quality Programs in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45349 through 45362). This RFI sought to update providers on CMS initiatives to make reporting of health disparities more comprehensive and actionable for LTCHs, providers, and patients. The RFI also invited public comment on future potential stratification of quality measures and improving demographic data collection. In response to the solicitation of public comment on future potential stratification and improving demographic data collection, commenters supported and recommended that CMS collect additional social and demographic data, like gender expression, disability status, language including English proficiency, housing security, food security, and forms of economic or financial insecurity to help provides address health equity in LTCHs. In addition, commenters suggested CMS use standardized data collection across agencies when incorporating health equity initiatives, while also expressing concern about the burden additional data collection efforts would place on providers (86 FR 45358).

Furthermore, we considered feedback we received when we proposed the creation of the SDOH category of standardized patient assessment data elements in the FY 2020 LTCH PPS proposed rule (84 FR 19545). Commenters were generally in favor of the concept of collecting SDOH items and noted the inclusion of additional SDOH would provide greater breadth and depth of data when developing policies to address social factors related to health. Many commenters also recommended including additional factors, such as food insecurity, housing insecurity, and independent living status, to ensure the full spectrum of social needs is examined. The FY 2020 LTCH PPS final rule (84 FR 42578 through 42581) includes a summary of the public comments that we received and our responses to those comments. We incorporated this input into the development of this proposal.

We invite comment on the proposal to adopt four new items as standardized patient assessment data elements under the SDOH category beginning with the FY 2028 LTCH QRP: one Living Situation item; two Food items; and one Utilities item.

e. Proposal To Modify the Transportation Item Beginning With the FY 2028 LTCH QRP

Beginning October 1, 2022, LTCHs began collecting seven standardized patient assessment data elements under the SDOH category on the LCDS.[521] One of these items, A1250. Transportation, collects data on whether a lack of transportation has kept a patient from getting to and from medical appointments, meetings, work, or from getting things they need for daily living. This item was adopted as a standardized patient assessment data element under the SDOH category in the FY 2020 LTCH PPS final rule (84 FR 42587). As we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42586), we continue to believe that access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management and the collection of a Transportation item would facilitate the connection to programs that can address identified needs.

As part of our routine item and measure monitoring work, we continually assess the implementation of the new SDOH items. We have identified an opportunity to improve the data collection for A1250. Transportation by aligning it with the Transportation category collected in our other programs.[522] [523] Specifically, we are proposing to modify the current Transportation item so that it aligns with a Transportation item collected on the AHC HRSN Screening Tool available to the IPFQR and IQR Programs.

A1250. Transportation currently collected in the LCDS asks: ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The response options are: (A) Yes, it has kept me from medical appointments or from getting my medications; (B) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; (C) No; (X) Patient unable to respond; and (Y) Patient declines to respond. The Transportation item collected in the AHC HRSN Screening Tool asks, ''In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The two response options are: (1) Yes; and (2) No. Consistent with the AHC HRSN Screening Tool, we are proposing

[519] National Council on Aging (NCOA). ''How to Make It Easier for Older Adults to Get Energy and Utility Assistance.'' Promising Practices Clearinghouse for Professionals. Jan 13, 2022. *https://www.ncoa.org/article/how-to-make-it-easier-for-older-adults-to-get-energy-and-utility-assistance.*

[520] This validated survey was developed as a clinical indicator of household energy security among pediatric caregivers. Cook, J.T., D.A. Frank., P.H. Casey, R. Rose-Jacobs, M.M. Black, M. Chilton, S. Ettinger de Cuba, et al. ''A Brief Indicator of Household Energy Security: Associations with Food Security, Child Health, and Child Development in US Infants and Toddlers.'' Pediatrics, vol. 122, no. 4, 2008, pp. e874–e875. *https://doi.org/10.1542/peds.2008-0286.*

[521] The seven SDOH items are ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 42577 through 42579).

[522] Centers for Medicare & Medicaid Services, FY2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[523] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49202 through 49215).

to modify the A1250. Transportation item currently collected in the LCDS in two ways: (1) revise the look-back period for when the patient experienced lack of reliable transportation; and (2) simplify the response options.

First, the proposed modification of the Transportation item would use a defined 12-month look back period, while the current Transportation item uses a look back period of six to 12 months. We believe the distinction of a 12-month look back period would reduce ambiguity for both patients and clinicians, and therefore improve the validity of the data collected. Second, we are proposing to simplify the response options. Currently, LTCHs separately collect information on whether a lack of transportation has kept the patient from medical appointments or from getting medications, and whether a lack of transportation has kept the patient from non-medical meetings, appointments, work, or from getting things they need. Although transportation barriers can directly affect a person's ability to attend medical appointments and obtain medications, a lack of transportation can also affect a person's health in other ways, including accessing goods and services, obtaining adequate food and clothing, and social activities.[524] The proposed modified Transportation item would collect information on whether a lack of reliable transportation has kept the patient from medical appointments, meetings, work *or* from getting things needed for daily living, rather than collecting the information separately. As discussed previously, we believe reliable transportation services are fundamental to a person's overall health, and as a result, the burden of collecting this information separately outweighs its potential benefit.

For the reasons stated, we are proposing to modify A1250. Transportation based on the Transportation item adopted for use in the AHC HRSN Screening Tool and adapted from the PRAPARE tool. The proposed Transportation item asks, ''In the past 12 months, has a lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The proposed response options are: (0) Yes; (1) No; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of the proposed Living Situation item to be adopted as a standardized patient assessment data element under the SDOH category can be found in the Downloads section of the LCDS and LTCH Manual web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

We invite comment on this proposal to modify the current Transportation item previously adopted as a standardized patient assessment data element under the SDOH category beginning with the FY 2028 LTCH QRP.

5. LTCH QRP Quality Measure Concepts Under Consideration for Future Years: Request for Information (RFI)

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the concepts under consideration listed in Table IX.E.–02 for future years in the LTCH QRP. In the FY 2024 LTCH PPS proposed rule (88 FR 27150–27153), we published a request for information (RFI) on the set of principles for selecting and prioritizing LTCH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. Within this proposed rule, we also sought input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing identified challenges. We refer readers to the FY 2024 LTCH PPS final rule (88 FR 59250–59252) for a summary of the public comments we received in response to the RFI.

Subsequently, our measure development contractor convened a Technical Expert Panel (TEP) on December 15, 2023 to obtain expert input on future measure concepts that could fill the measurement gaps identified in the FY 2024 RFI.[525] The TEP discussed the alignment of PAC and Hospice measures with CMS's ''Universal Foundation'' of quality measures.[526] The Universal Foundation aims to focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

In consideration of the feedback we received through these activities, we are seeking input on three measure concepts for the LTCH QRP. One is a composite of vaccinations,[527] which could represent overall immunization status of LTCH patients such as the Adult Immunization Status measure [528] in the Universal Foundation. A second concept we are seeking feedback on is the concept of depression for the LTCH QRP, which may be similar to the Clinical Screening for Depression and Follow-up measure [529] in the Universal Foundation. Finally, we are seeking feedback on the concept of pain management.

TABLE IX.E.-02: FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Quality Measure Concepts
Vaccination Composite
Pain Management
Depression

While we will not be responding to specific comments in response to this RFI in the FY 2025 LTCH PPS final rule, we intend to use this input to inform our future measure development efforts.

[524] Centers for Medicare & Medicaid Services, FY2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[525] The Post-Acute Care (PAC) and Hospice Quality Reporting Program Cross-Setting TEP summary report will be published in early summer or as soon as technically feasible. LTCHs can monitor the Partnership for Quality Measurement website at *https://mmshub.cms.gov/get-involved/technical-expert-panel/updates for updates.*

[526] Centers for Medicare & Medicaid Services. Aligning Quality Measures Across CMS—the Universal Foundation. November 17, 2023. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

[527] A composite measure can summarize multiple measures through the use of one value or piece of information. More information can be found at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/mms/downloads/composite-measures.pdf.*

[528] CMS Measures Inventory Tool. Adult immunization status measure found at *https://cmit.cms.gov/cmit/#/FamilyView?familyId=26.*

[529] CMS Measures Inventory Tool. Clinical Depression Screening and Follow-Up measure found at *https://cmit.cms.gov/cmit/#/FamilyView?familyId=672.*

6. Future LTCH Star Rating System: Request for Information (RFI)

Section 1886(m)(5)(E) of the Act requires that the Secretary establish procedures for making data submitted under the LTCH QRP available to the public. Such procedures must ensure the LTCHs participating in the LTCH QRP have the opportunity to review the LTCH-submitted data prior to such data being made public. The Secretary must publicly report quality measures that relate to services furnished in LTCHs on the CMS website. We currently publicly report data we receive on measures under the LTCH QRP on our Care Compare website.[530]

Care Compare displays star ratings for many provider types, specifically: doctors and clinicians, hospitals, nursing homes, home health, hospice, and dialysis facilities. Rating methodologies vary by provider type. Star ratings summarize performance using symbols to help consumers quickly and easily understand quality of care information. Star ratings are designed to enhance and supplement existing publicly reported quality information, and also serve to spotlight differences in health care quality and identify areas for improvement.[531] Some providers receive ''overall star ratings,'' which are a composite score calculated using different data sources, such as quality measures or survey results. Others receive ''patient survey star ratings,'' a composite score derived from patient experience of care surveys. Depending on the provider type, some utilize one—or both—of these rating methodologies.

Star ratings serve an important function for patients, caregivers, and families, helping them to more quickly comprehend complex information about a health care providers' care quality and to easily assess differences among providers. This transparency serves an important educational function, while also helping to promote competition in health care markets. Informed patients and consumers are more empowered to select among health care providers, fostering continued quality improvement. CMS' commitment to establishing star ratings systems across health care settings is consistent with the Biden-Harris Administration's goal to promote an open, transparent, and competitive economy as outlined in President Biden's July 2021 Executive Order on Promoting Competition in the American Economy.[532]

We are seeking feedback on the development of a five-star methodology for LTCHs that can meaningfully distinguish between quality of care offered by providers. Star ratings for LTCHs will be designed to help consumers quickly identify differences in quality when selecting a provider. We are committed to developing a well-tested, data-driven methodology that encourages continuous quality improvement. We plan to engage with the LTCH community and provide multiple opportunities for LTCHs and other interested parties to give input on the development of a star rating system for LTCHs. Additionally, LTCHs would have the ability to preview their own facility's quality data before public posting of the LTCH's star rating on the Care Compare website in accordance with section 1886(j)(7)(E) of the Act.

We invite general comments on a potential star rating system as well as measures suitable to use in a star rating system. Specifically, we invite public comment on the following questions:

- Are there specific criteria CMS should use to select measures for a star rating system?
- How should CMS present star ratings information in a way that it is most useful to consumers?

While we will not be responding to specific comments in response to this RFI in the FY 2025 IPPS/LTCH PPS final rule, we intend to use this input to inform our future star rating development efforts. We intend to consider how a rating system would determine an LTCH's star rating, the methods used for such calculations, and an anticipated timeline for implementation. We will consider comments in response to this RFI for future rulemaking.

7. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting specified data for the LTCH QRP.

b. Proposed Reporting Schedule for the Submission of Proposed New Items as Standardized Patient Assessment Data Elements and the Modified Transportation Item Beginning With the FY 2028 LTCH QRP

As discussed in section X.4. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category (one Living Situation item, two Food items, and one Utilities item), and to modify the Transportation standardized patient assessment data elements previously adopted under the SDOH category beginning with the FY 2028 LTCH QRP.

We are proposing that LTCHs would be required to report these new items and the modified Transportation item using the LCDS beginning with patients admitted on October 1, 2026 for purposes of the FY 2028 LTCH QRP. Starting in CY 2027, LTCHs would be required to submit data for the entire calendar year for purposes of the FY 2029 LTCH QRP.

We are also proposing that LTCHs who submit the Living Situation, Food, and Utilities items proposed for adoption as standardized patient assessment data elements under the SDOH category with respect to admission only would be deemed to have submitted those items with respect to both admission and discharge. We propose that LTCHs would be required to submit these items at admission only (and not at discharge), because it is unlikely that the assessment of those items at admission will differ from the assessment of the same item at discharge. This would align the data collection for these proposed items with other SDOH items (that is, Race, Ethnicity, Preferred Language, and Interpreter Services) which are only collected at admission.[533] A draft of the proposed items is available in the Downloads section of the LCDS and LTCH Manual web page at *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

As we noted in Section X.E,4.e. of the preamble of this proposed rule, we continually to assess the implementation of the new SDOH items, including A1250. Transportation, as part of our routine item and measure monitoring work. We received feedback from stakeholders in response to the FY 2020 LTCH PPS proposed rule (84 FR 19551) noting their concern with the burden of collecting the Transportation item at admission and discharge.

[530] Centers for Medicare & Medicaid Services (CMS). Care Compare. 2023. *https://www.medicare.gov/care-compare.*

[531] Centers for Medicare & Medicaid Services (CMS). *Home Health Star Ratings.* 2023. *https://www.cms.gov/medicare/quality/home-health/home-health-star-ratings.*

[532] Executive Order on Promoting Competition in the American Economy | The White House.

[533] FY 2020 IPPS/LTCH PPS final rule (84 FR 42588 through 42590).

Specifically, commenters stated that a patient's access to transportation is unlikely to change between admission and discharge. We analyzed the data LTCHs reported from October 1, 2022 to June 30, 2023 (Q4 CY 2022 through Q2 CY 2023) and found that patient responses did not significantly change from admission to discharge.[534] Specifically, the proportion of patients [535] who responded ''Yes'' to the Transportation item at admission versus at discharge differed by only 1.65 percentage points during this period. We find these results convincing, and therefore are proposing to require LTCHs to collect and submit the proposed modified standardized patient assessment data element, Transportation, at admission only.

We invite public comment on our proposal to collect data on the following items proposed as standardized patient assessment data elements under the SDOH category at admission beginning October 1, 2026 with the FY 2028 LTCH QRP: (1) Living Situation as described in section X.4.c.(1) of this proposed rule; (2) Food as described in section X.4.c.(2) of this proposed rule; and (3) Utilities as described in section X.4.c.(3) of this proposed rule. We also invite comment on our proposal to submit the proposed modified standardized patient assessment data element, Transportation, at admission only beginning October 1, 2026 with the FY 2028 LTCH QRP as described in section IX.4.e. of this proposed rule.

c. Proposal To Modify the LCDS Admission Assessment Window to Four Days Beginning With the FY 2028 LTCH QRP

Since the FY2012 IPPS/LTCH Final Rule, LTCHs have collected information for the LTCH QRP utilizing the LCDS.[536] Since 2012, the LTCH QRP has evolved in response to both quality initiatives and statutory requirements, and as a result, the LCDS has evolved to support data collection for evaluation of health outcomes in the LTCH. The LCDS Version 5.0 was implemented on October 1, 2022, and is currently in use.[537]

As specified in the LCDS Manual, the LCDS Admission assessment has a maximum three-day assessment period, beginning with the date of admission, in which the patient's assessment must be conducted to obtain information for the LCDS Admission assessment items. All LTCHs are required to record the Assessment Reference Date (ARD) (A0210) on each LCDS, which is defined as the end point of the assessment period for the LCDS assessment record. LTCHs can set their own ARD, as long as it is no later than the third calendar day (date of admission plus two calendar days) of the patient's stay.

We continually look for opportunities to minimize LTCHs' burden associated with collection of the LCDS through strategies that include improving communication and conducting outreach with users, as well as simplifying collection and submission requirements. In recent years, we have received feedback regarding the difficulty of collecting the required LCDS data elements within the three-day assessment window when medically complex patients are admitted prior to and on weekends. On October 17th, 2023, our measure development contractor hosted an LTCH Listening Session on the Administrative Burden of the LTCH QRP, and invited providers to comment on several LTCH QRP topics, including a potential expansion of the assessment period to four days.[538] During the listening session, we received support for revising the Admission assessment window, with participants suggesting that extending the assessment window would ease the difficulties noted above.

We propose to extend the Admission assessment period from three days to four days, beginning with LTCH admissions on October 1, 2026. For example, if a patient was admitted on Friday, October 19, the ARD for the LCDS Admission assessment could be no later than Monday, October 22. This change to the assessment period would only apply to the LCDS Admission assessment, and have no impact on burden.

We invite public comment on our proposal to extend the LCDS Admission assessment window from three to four days beginning with the FY 2028 LTCH QRP.

8. Policies Regarding Public Display of Measure Data for the LTCH QRP

We are not proposing any new policies regarding the public display of measure data at this time. For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

F. Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Social Security Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub. L. 111–5) authorize downward payment adjustments under Medicare, beginning with fiscal year (FY) 2015 for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for the applicable electronic health record (EHR) reporting periods. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added subsection (d) hospitals in Puerto Rico as eligible hospitals under the Medicare EHR Incentive Program and extended the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for section (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting periods.

2. Proposal To Change the Antimicrobial Use and Resistance (AUR) Surveillance Measure Beginning With the EHR Reporting Period in Calendar Year (CY) 2025

a. Proposal To Modify the AUR Surveillance Measure Beginning With the EHR Reporting Period in CY 2025

The Medicare Promoting Interoperability Program encourages healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange objective. In the FY 2023 Hospital Inpatient Prospective Payment System

[534] Due to data availability of LTCH SDOH standardized patient assessment data elements, this is based on three quarters of Transportation data.

[535] The analysis is limited to patients who responded to the Transportation item at both admission and discharge.

[536] Office of the Federal Register of the National Archives and Records Administration and the U.S. Government Publishing Office. *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment.* 2011. *https://www.federalregister.gov/d/2011-19719/p-3517.*

[537] Centers for Medicare & Medicaid Services (CMS). *Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) & LCDS Manual.* 2023. *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

[538] A summary of the LTCH Listening Session can be found on the LTCH QRP Measures Information web page at: *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-quality-reporting-measures-information.*

and Long Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule, we finalized the requirement for eligible hospitals and CAHs to report the AUR Surveillance measure with a modification to begin reporting with the EHR reporting period in CY 2024 (87 FR 49337). Under the AUR Surveillance measure, eligible hospitals and CAHs report two kinds of data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN): Antimicrobial Use (AU) data and Antimicrobial Resistance (AR) data (87 FR 49335). Separate data elements and technical capabilities are required for reporting the AU data and AR data, and we refer readers to the CDC NHSN AUR protocols for technical details regarding implementation.[539] Eligible hospitals and CAHs that report a ''yes'' response indicate that they have submitted data for both AU and AR, and will receive credit for reporting the measure, unless they claim an exclusion for which they are eligible. Eligible hospitals and CAHs must also use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting'' for data submission (87 FR 49337).

After finalization of the AUR Surveillance measure, we received feedback from some eligible hospitals and CAHs seeking clarity regarding reporting requirements and exclusion eligibility for eligible hospitals and CAHs. Comments and questions included whether eligible hospitals or CAHs with an eligible exclusion preventing their participation in reporting either AU data or AR data were required or able to report any available data to receive credit under the AUR Surveillance measure. Under our current policy, if an eligible hospital or CAH meets the exclusion criteria with respect to reporting either AU data or AR data, the hospital is excluded from the entire AUR Surveillance measure (87 FR 49337).

In collaboration with the CDC, we identified the need to separate the AUR Surveillance measure into two measures to clarify reporting requirements and incentivize greater data reporting from eligible hospitals and CAHs. In addition, because AU and AR reporting rely on different data sources, such as an electronic medication administration record (eMAR)/bar-coded medication administration (BCMA) for AU, and lab information systems (LISs) for AR, we also believe that separating the measure into two measures would more appropriately target the availability of exclusions for participants who have difficulty with data transmission using a single data source.

Specifically, we are proposing to separate the AUR Surveillance measure into two measures, beginning with the EHR reporting period in CY 2025:

- *AU Surveillance measure:* The eligible hospital or CAH is in active engagement with CDC's NHSN to submit AU data for the selected EHR reporting period and receives a report from NHSN indicating its successful submission of AU data for the selected EHR reporting period.
- *AR Surveillance measure:* The eligible hospital or CAH is in active engagement with CDC's NHSN to submit AR data for the selected EHR reporting period and receives a report from NHSN indicating its successful submission of AR data for the selected EHR reporting period.

Under the proposed AU Surveillance measure, eligible hospitals and CAHs would be required to report AU data to CDC's NHSN. Under the proposed AR Surveillance measure, eligible hospitals and CAHs would also be required to report AR data to CDC's NHSN. Under this proposal, eligible hospitals and CAHs must report a ''yes'' response or claim an exclusion, separately, to receive credit for reporting the AU Surveillance measure and the AR Surveillance measure. For both measures, we propose that eligible hospitals and CAHs be required to use technology certified to the Office of the National Coordinator for Health Information Technology (ONC) Certification Program for Health Information Technology (health IT) certification criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting,'' as they are for the AUR Surveillance measure. We believe that separating the AUR Surveillance measure into two measures would encourage participation from eligible hospitals and CAHs that could report data for only the AU measure or for only the AR measure that might previously have been excluded because of their inability to report both AU data and AR data as required by the AUR Surveillance measure.

Under current policy with a single AUR Surveillance measure, eligible hospitals and CAHs that meet the exclusion criteria with respect to reporting data of one kind (for example, AR) are excluded from all AUR Surveillance measure reporting requirements, even if they can report data of the other kind (for example, AU). Offering a complete AUR Surveillance measure exclusion, even when participants can report either AU or AR data, is contrary to the goals of the Public Health and Clinical Data Exchange objective, because it discourages the sending of partial data as available. Separating the single AUR Surveillance measure into two measures would better reflect the reality that AU data reporting and AR data reporting rely on different data sources that require different types of exclusions to reflect the separate clinical and data domains of prescribing and microbiological testing. Separation of AU data reporting and AR data reporting into two measures also supports the Medicare Promoting Interoperability Program's administrative requirements with respect to scoring, because the current scoring methodology for the Public Health and Clinical Data Exchange objective does not grant partial credit for reporting on individual measures. We note that the separation of the AUR Surveillance measure does not expand on the previously finalized requirements of the measure; the proposed separation from one measure into two measures allows eligible hospitals and CAHs the opportunity to submit data for either AU or AR if it can only submit data for one of the two, versus an all or nothing approach.

We invite public comment on our proposal to separate the AUR Surveillance measure into two measures, AU Surveillance and AR Surveillance, beginning with the EHR reporting period in CY 2025.

b. Proposal To Adopt Exclusions for the AU Surveillance Measure and the AR Surveillance Measure Beginning With the EHR Reporting Period in CY 2025

We previously finalized the availability of three exclusions for an eligible hospital or CAH reporting on the AUR Surveillance measure that: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have an eMAR/BCMA records or an electronic admission discharge transfer (ADT) system during the EHR reporting period; or (3) Does not have an electronic LIS or electronic ADT system during the EHR reporting period (87 FR 49337).

We have received feedback from eligible hospitals and CAHs requesting clarity on whether an AUR Surveillance exclusion applies when they possess all necessary health IT systems but lack discrete electronic access to data elements necessary for NHSN AUR reporting. For example, an eligible

[539] *https://www.cdc.gov/nhsn/psc/aur/index.html.*

hospital or CAH may possess an LIS, but it may refer AR testing to an outside reference laboratory that does not provide data elements necessary for NHSN AUR reporting results to the referring laboratory. As the eligible hospital or CAH has an LIS system and therefore could not claim the third exclusion, assuming it could not claim another exclusion, the eligible hospital or CAH would be required to manually extract the data elements to successfully report the AUR Surveillance measure.

Our current policy inadvertently causes difficulties for eligible hospitals and CAHs such as the one in the example because manual reporting of NHSN AUR data is both infeasible and against NHSN AUR recommendations.[540] In addition, we require that eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), ''Transmission to public health agencies—antimicrobial use and resistance reporting'' for data submission (87 FR 49337). We believe an exclusion that applies to eligible hospitals and CAHs that lack discrete electronic access to required data elements, including interface or configuration issues beyond their control, would address the difficulties for eligible hospitals and CAHs engaging in manual data collection to conduct AU or AR reporting. Therefore, we are proposing to add a new exclusion to account for scenarios where eligible hospitals or CAHs lack a data source containing discrete electronic data elements that are required for reporting the AUR Surveillance measure, meaning an eligible hospital or CAH cannot query, extract, or download the data elements in a discrete, structured manner from the systems to which it has access. Specifically, under this new exclusion, an eligible hospital or CAH would be excluded from reporting the AUR Surveillance measure when it does not have a data source containing the minimal discrete data elements that are required for reporting.

Should we finalize our proposal to separate the AUR Surveillance measure into two separate measures, AU Surveillance and AR Surveillance, we propose modifying the existing exclusions under the AUR measure, to maintain applicability to the AU measure and AR measure. For example, we propose to assign current exclusion 2 to the AU Surveillance measure because it relies on eMAR/BCMA data, and current exclusion 3 to the AR Surveillance measure because it relies on LIS data.

Should we finalize our previously discussed proposal to add a new exclusion for the eligible hospitals and CAHs that lack discrete electronic access to data elements that are required for reporting, we propose that the new exclusion would be available for both the AU Surveillance measure and the AR Surveillance measure. Specifically, for the AU Surveillance measure, we propose to adopt three eligible exclusions, as follows: Any eligible hospital or CAH may be excluded from the AU Surveillance measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have an eMAR/BCMA electronic records or an electronic ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting. For the AR Surveillance measure, we propose to adopt three eligible exclusions, as follows: Any eligible hospital or CAH may be excluded from the AR Surveillance measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have an electronic LIS or electronic ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.

We invite public comment on our proposals to adopt three eligible exclusions for the proposed AU Surveillance measure and for the AR Surveillance measure, of which the third exclusion for each measure is a new exclusion for eligible hospitals and CAHs that lack discrete electronic access to data elements that are required for reporting.

c. Proposal To Adopt Active Engagement for the Proposed AU Surveillance Measure and AR Surveillance Measure Beginning With the EHR Reporting Period in CY 2025

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to limit the amount of time an eligible hospital or CAH may spend in the Option 1: Pre-production and Validation level of active engagement to one EHR reporting period (87 FR 49340 through 49342). As finalized, this limitation applies beginning with the EHR reporting period in CY 2024. Should we finalize our proposal to modify the AUR Surveillance measure into two new measures, AU Surveillance and AR Surveillance, we propose to treat these two measures as new measures with respect to active engagement, beginning with the EHR reporting period in CY 2025 and subsequent years.

We propose to evaluate the level of active engagement for the AU Surveillance and AR Surveillance measures beginning with the EHR reporting period in CY 2025, independent of the participant's prior level of active engagement for the AUR Surveillance measure in the EHR reporting period in CY 2024. If we finalize the AU Surveillance and AR Surveillance measures, we are proposing that for each measure, eligible hospitals and CAHs may spend only one EHR reporting period at the Option 1: Pre-production and Validation level of active engagement, and they must progress to the Option 2: Validated Data Production level for the next EHR reporting period for which they report the measure.

This proposal would offer eligible hospitals and CAHs an additional year to gain familiarity with reporting in the NHSN AUR Module before they are required to participate in Option 2: Validated Data Production, and if finalized, the AU Surveillance and AR Surveillance measures.

We invite public comment on our proposal to evaluate the level of active engagement for the proposed AU Surveillance and AR Surveillance measures, independent of the participant's prior active engagement for the AUR Surveillance measure.

d. Proposal To Maintain the Scoring Approach for Reporting Required Measures in the Public Health and Clinical Data Exchange Objective Beginning With the EHR Reporting Period in CY 2025

Should we finalize our proposal to separate the AUR Surveillance measure into two measures, AU Surveillance and AR Surveillance, we do not believe this change should affect scoring or the exclusion redistributions for the Public Health and Clinical Data Exchange objective, previously adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59266). We note that the separation of the AUR Surveillance measure does not expand on the previously finalized requirements of the measure. In other words, eligible hospitals and CAHs are required to report AU and AR data, whether combined under the AUR Surveillance measure, or separated into AU Surveillance and AR Surveillance measures.

Therefore, we propose to maintain a scoring value of 25 points for reporting

[540] *https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf.*

all required measures in the Public Health and Clinical Data Exchange objective, which would increase from five measures to six measures, including the four previously finalized measures and the two proposed required measures (AU Surveillance and AR Surveillance). We also propose to maintain the exclusion redistribution policy we adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59267) but modify it to indicate there are six measures as opposed to five measures. If an eligible hospital or CAH claims an exclusion for each of the six required measures, the 25 points of the Public Health and Clinical Data Exchange objective would continue to be redistributed to the Provide Patients Electronic Access to their Health Information measure.

We invite public comment on our proposals to maintain the current approach to scoring and points redistribution for the proposed AU Surveillance and AR Surveillance measures.

3. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2025

For ease of reference, Table IX.F.–01 lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025, as revised, to reflect the proposals in this proposed rule.

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TABLE [IX.F.-01.]: SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2025

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2025 and subsequent years
Electronic Prescribing (e-Prescribing)	e-Prescribing: For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT.*	The number of prescriptions in the denominator generated and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed, other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions, and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
e-Prescribing	Query of Prescription Drug Monitoring Program (PDMP): For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	(1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. (2) Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	N/A (measure is Y/N)

Health Information Exchange (HIE)	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
HIE	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

HIE	HIE Bi-Directional Exchange The eligible hospital or CAH must attest to the following: (*1*) Participating in an IIIE in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

HIE	Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

	this Framework Agreement.				
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital's or CAH's CEHRT.	The number of patients in the denominator (or patient authorized representatives) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry or immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data are collected by its jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)

Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit syndromic surveillance data from an emergency department (POS 23).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)

Public Health and Clinical Data Exchange	Electronic Case Reporting (eCR): The eligible hospital or CAH is in active engagement with a PHA to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving eCR data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive eCR data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)

Public Health and Clinical Data Exchange	Electronic Reportable Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit ELR results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the ELR result measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	AU Surveillance**: The eligible hospital or CAH is in active engagement with CDC's NHSN to submit AU data for the EHR reporting period and receives a report from NHSN indicating its successful submission of AU data for the EHR reporting period.**	N/A (measure is Y/N)**	N/A (measure is Y/N)**	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have eMAR/BCMA electronic records or an ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.**	N/A (measure is Y/N)**
Public Health and Clinical Data Exchange	AR Surveillance**: The eligible hospital or CAH is in active engagement with	N/A (measure is Y/N)**	N/A (measure is Y/N)**	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have	N/A (measure is Y/N)**

	CDC's NHSN to submit AR data for the EHR reporting period and receives a report from NHSN indicating its successful submission of AR data for the EHR reporting period.**			any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have an LIS or ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.**	
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)
Protect Patient Health Information	Security Risk Analysis Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3),	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

	implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.				
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience (SAFER) Guides Conduct an annual self-assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)

* In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59269) we inadvertently omitted a footnote describing changes to the phrasing of the measure description and description of the numerator in this Table to align with the technical update finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49327).

** Signifies a proposal made in this FY 2025 IPPS/LTCH PPS proposed rule that would apply to the EHR reporting period in CY 2025 and subsequent years.

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4. Updates to the Definition of CEHRT in the Medicare Promoting Interoperability Program Beginning With the EHR Reporting Period in CY 2024

In the CY 2024 Medicare Physician Fee Schedule (PFS) final rule (88 FR 79307 through 79312), we finalized revisions to the definition of CEHRT for the Medicare Promoting Interoperability Program at 42 CFR 495.4. Specifically, we finalized the addition of a reference to the revised name of ''Base EHR definition,'' proposed in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) proposed rule (88 FR 23759, 23905), to ensure, if the HTI–1 proposals were finalized, the revised name of ''Base EHR definition'' would be applicable for the CEHRT definitions going forward (88 FR 79309 through 79312). We also finalized the replacement of our references to the ''2015 Edition health IT certification criteria'' with ''ONC health IT certification criteria,'' and the addition of the regulatory citation for ONC health IT certification criteria in 45 CFR 170.315. We finalized the proposal to specify that technology meeting the CEHRT definition must meet ONC's health IT certification criteria ''as adopted and updated in 45 CFR 170.315'' (88 FR 79553). This approach is consistent with the definitions subsequently finalized in ONC's HTI–1 final rule, which appeared in the **Federal Register** on January 9, 2024 (89 FR 1205 through 1210). For additional background and information on this update, we refer readers to the discussion in the CY 2024 PFS final rule on this topic (88 FR 79307 through 79312).

In consideration of the updates finalized in the CY 2024 PFS final rule and the HTI–1 final rule, we refer to ''ONC health IT certification criteria'' throughout this proposed rule where we previously would have referred to ''2015 Edition health IT certification criteria.'' We believe that these revisions to the definition of CEHRT in 42 CFR 495.4 will ensure that updates to the definition of Base EHR in 45 CFR 170.102, and updates to applicable ONC health IT certification criteria in 45 CFR 170.315, will be incorporated into the CEHRT definition without additional regulatory action by CMS. We also believe these updates align with the transition, where the ONC health IT certification criteria were adopted as year themed ''editions,'' to the ''edition-less approach finalized in the ONC HTI–

1 final rule. For ease of reference, Table IX.F.–02. lists the ONC health IT certification criteria required to meet the Medicare Promoting Interoperability Program objectives and measures.

We also wish to highlight certain updates to ONC health IT certification criteria finalized in the ONC HTI–1 final rule that impact certification criteria referenced under the CEHRT definition. ONC adopted the certification criterion, ''decision support interventions (DSI)'' in 45 CFR 170.315(b)(11) to replace the ''clinical decision support (CDS)'' certification criterion in 170.315(a)(9) included in the Base EHR definition (89 FR 1231). The finalized DSI criterion ensures that Health IT Modules certified to 45 CFR 170.315(b)(11) must, among other functions, enable a limited set of identified users to select (activate) evidence-based and Predictive DSIs (as defined in 45 CFR 170.102) and support ''source attributes''—categories of technical performance and quality information—for both evidence-based and Predictive DSIs. ONC further finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS version of the certification criterion in 45 CFR 170.315(a)(9), or being certified to the revised DSI criterion in 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that only the DSI criterion in 45 CFR 170.315(b)(11) will be included in the Base EHR definition, and the adoption of the criterion in 45 CFR 170.315(a)(9) will expire on January 1, 2025 (89 FR 1281).

In addition to the DSI criterion, which is required to meet the Base EHR definition after January 1, 2025, ONC finalized other updates related to health IT certification criteria referenced in the CEHRT definition in the HTI–1 final rule. For these updates, health IT developers must update and provide certified Health IT Modules to their customers by January 1, 2026, including updates resulting from the following finalized policies:

- ONC updated the ''Transmission to public health agencies—electronic case reporting'' criterion in 45 CFR 170.315(f)(5) specifying consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion (89 FR 1226).
- ONC adopted the United States Core Data for Interoperability (USCDI) version 3 in 45 CFR 170.213(b) and finalized that USCDI version 1 in 45 CFR 170.213(a) will expire on January 1, 2026. This change impacts ONC health IT certification criteria that reference the USCDI, including the ''transitions of care'' certification criteria in 45 CFR 170.315(b)(1)(iii)(A)(*1*)–(*2*), ''Clinical information reconciliation and incorporation—Reconciliation'' (45 CFR 170.315(b)(2)(iii)(D)(1) through (3)); and ''View, download, and transmit to 3rd party'' (45 CFR 170.315(e)(1)(i)(A)(*1*)) (89 FR 1210).
- ONC updated the ''demographics'' certification criterion (45 CFR 170.315(a)(5)), including renaming the criterion to ''patient demographics and observations'' (89 FR 1295).
- ONC updated the ''standardized API for patient and population services'' certification criterion in 45 CFR 170.315(g)(10) to include newer versions of certain standards and updated functionality to support the criterion (89 FR 1283).

For complete information about the updates to ONC health IT certification criteria finalized in the HTI–1 Final Rule, we refer readers to the text of the final rule (89 FR 1192) as well as resources available on ONC's website.[541]

[541] For more information, see: *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

TABLE IX.F.-02.: MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	ONC Health IT Certification Criteria as defined in the following sections of Title 45 CFR
e-Prescribing	e-Prescribing	170.315(b)(3) e-Prescribing
	Query of PDMP	170.315(b)(3) e-Prescribing
HIE	Support electronic referral loops by sending health information	170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	170.315(b)(1) Transitions of care
		170.315(b)(2) Clinical information reconciliation and incorporation
HIE (alternative)	HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		170.315(b)(1) Transitions of care
		170.315(b)(2) Clinical information reconciliation and incorporation
		170.315(g)(7) Application access — patient selection
		170.315(g)(9) Application access — all data request
		170.315(g)(10) Application access — standardized API for patient and population services
HIE (alternative)	Participation in TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		170.315(b)(1) Transitions of care
		170.315(b)(2) Clinical information reconciliation and incorporation
		170.315(g)(7) Application access — patient selection
		170.315(g)(9) Application access — all data request
		170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	170.315(e)(1) View, download, and transmit to 3rd party
		170.315(g)(7) Application access — patient selection
		170.315(g)(9) Application access — all data request
		170.315(g)(10) Application access — standardized API for patient and population services

Public Health and Clinical Data Exchange	Immunization registry reporting	170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No ONC health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
	AU Surveillance*	170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
	AR Surveillance*	170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
Electronic Clinical Quality measures (eCQMs)	eCQMs for eligible hospitals and CAHs	170.315(c)(1)
		170.315(c)(2)
		170.315(c)(3)(i) and (ii)
Protect Patient Health Information	Security Risk Assessment	No ONC health IT certification criteria at this time.
	SAFER Guides	No ONC health IT certification criteria at this time.

*Signifies a proposal made in this FY 2025 IPPS/LTCH PPS proposed rule.

5. Proposal To Change the Scoring Methodology Beginning With the EHR Reporting Period in CY 2025

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a performance-based scoring methodology for eligible hospitals and CAHs reporting under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, which included a minimum scoring threshold of a total score of 50 points or more, that eligible hospitals and CAHs must meet to satisfy the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45491 through 45492), we increased the minimum scoring threshold from 50 to 60 points beginning with the EHR reporting period in CY 2022 and adopted corresponding changes to the regulatory text at 42 CFR 495.24(e)(1)(i)(C) for the EHR reporting period in CY 2022. In the FY 2023 IPPS/LTCH PPS final rule, we extended the 60-point threshold for the EHR reporting period in CY 2023 and subsequent years in the regulatory text at 42 CFR 495.24(f)(1)(i)(B) (87 FR 49410 through 49411).

For the EHR reporting period in CY 2025 and subsequent years, we are proposing to increase the minimum scoring threshold from 60 points to 80 points and are proposing corresponding changes to the regulation text at 42 CFR 495.24(f)(1)(i). Our review of the CY 2022 Medicare Promoting Interoperability Program's performance results found 98.5 percent of eligible hospitals and CAHs (that is 97 percent of CAHs and 99 percent of eligible hospitals) that reported to the Medicare Promoting Interoperability Program successfully met the minimum threshold score of 60 points, and 81.5 percent of eligible hospitals and CAHs (that is 78 percent of CAHs and 83 percent of eligible hospitals) that reported to the Medicare Promoting Interoperability Program exceeded the score of 80 points. Given the widespread success of eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program in CY 2022, we believe that by adopting a

higher scoring threshold, we would incentivize more eligible hospitals and CAHs to align their health information systems with evolving industry standards and would encourage increased data exchange. We note that eligible hospitals and CAHs would have gained3 years of experience in the Medicare Promoting Interoperability Program (CYs 2022, 2023, and 2024) at the 60-point minimum score threshold to improve performance. We believe an increase from 60 points to 80 points would encourage higher levels of performance through the advanced use of CEHRT to further incentivize eligible hospitals and CAHs to improve interoperability and health information exchange. We are also proposing to make corresponding changes to the regulatory text at 42 CFR 495.24(f)(1)(i) to reflect our proposed scoring threshold change and, if finalized, this would take effect for the EHR reporting period in CY 2025 and subsequent years. Specifically, we propose to adopt 42 CFR 495.24(f)(1)(i)(C), which states ''In 2025 and subsequent years, earn a total score of at least 80 points.''

We invite public comment on our proposal to increase the minimum scoring threshold from 60 points to 80 points for the EHR reporting period in CY 2025 and subsequent years, and to make corresponding changes to the regulatory text at 42 CFR 495.24(f)(1)(i).

As shown in Table [IX.F.–03.], the points associated with the required measures sum to 100 points, and reporting one of the optional measures under the Public Health and Clinical Data Exchange Objective adds an additional 5 bonus points. The scores for each of the measures are added together to calculate a total score of up to 100 possible points for each eligible hospital or CAH. We refer readers to Table [IX.F.–03.] in this proposed rule, which reflects the objectives, measures, maximum points available, and whether a measure is required or optional for the EHR reporting period in CY 2025 based on our previously adopted policies, and the proposals included in this proposed rule.

TABLE IX.F.-03: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN CY 2025 AND SUBSEQUENT YEARS

Objective	Measure	Maximum Points	Required/Optional
e-Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
HIE	Support Electronic Referral Loops by Sending Health Information	15 points	Required (eligible hospitals and CAHs must choose one of the three reporting options)
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	HIE Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following six measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • eCR • Electronic Reportable Laboratory Result Reporting • AU Surveillance* • AR Surveillance*	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) are required but will not be scored. Reporting eCQMs is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at the Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement.

*Signifies a proposal made in this FY 2025 IPPS/LTCH PPS proposed rule. For details on our proposal to modify the AUR Surveillance measure, we refer readers to section IX.F.2 of this proposed rule.

The maximum points available, by measure, in this proposed rule, as shown in Table IX.F.–03, do not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We are not proposing any changes to our policy for point redistribution in the event an exclusion is claimed. We refer readers to Table IX.F.–04 in this proposed rule, which shows how points would be redistributed among the objectives and measures for the EHR reporting period in CY 2025, in the event an eligible hospital or CAH claims an exclusion.

TABLE IX.F.-04: EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2025 AND SUBSEQUENT YEARS

Objective	Measure	Redistribution if Exclusion is Claimed
e-Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
HIE	Support Electronic Referral Loops by Sending Health Information	No exclusion
	-AND-	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	No exclusion
	-OR-	
	HIE Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following six measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • eCR • Electronic Reportable Laboratory Result Reporting • AU Surveillance* • AR Surveillance*	If an exclusion is claimed for each of the six measures, 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information measure

*Signifies a proposal made in this FY 2025 IPPS/LTCH PPS proposed rule.

6. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Proposal To Update Clinical Quality Measures and Reporting Requirements in Alignment With the Hospital Inpatient Quality Reporting (IQR) Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Social Security Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures selected by CMS using CEHRT (also referred to as eCQMs), as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

Tables IX.F.–05. and IX.F.–06 in this proposed rule summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the CY 2024 and CY 2025 reporting periods, as finalized in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59280 through 59281). To maintain alignment with the Hospital IQR program, in sections IX.C.5.c and IX.C.5.d of the preamble of this proposed rule, the order of the eCQMs displayed in Tables IX.F.–05 and IX.F.–06 mirrors that of the Hospital IQR program. In addition, the short names and the CBE numbers of the measures in the tables match the measures on the Electronic Clinical Quality Improvement Resource Center website at: *https://ecqi.healthit.gov/.*

TABLE IX.F.-05: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE REPORTING PERIOD

Short Name	Measure Name	Consensus-based entity (CBE) #
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia	3533e
HH-ORAE	Hospital Harm - Opioid-Related Adverse Events	3501e
GMCS	Global Malnutrition Composite Score	3592e

TABLE IX.F.-06: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2025 REPORTING PERIOD

Short Name	Measure Name	CBE #
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm - Severe Hypoglycemia	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia	3533e
HH-OREA	Hospital Harm - Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm - Pressure Injury	3498e
HH-AKI	Hospital Harm - Acute Kidney Injury	3713e
GMCS	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)	3663e

(2) Proposal To Adopt eCQMs

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479), we intend to continue to align the eCQM reporting requirements and eCQM measure set for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program, to the extent feasible.

As discussed in the sections IX.C.5.c and IX.C.5.d of this proposed rule with respect to the Hospital IQR Program, we are proposing to adopt two new eCQMs for the Medicare Promoting Interoperability Program and to modify one eCQM, beginning with the CY 2026 reporting period. Specifically, we propose to add the following two eCQMs to the Medicare Promoting Interoperability Program eCQM measure set from which eligible hospitals and CAHs could self-select to report, beginning with the CY 2026 reporting period: (1) the Hospital Harm—Falls

with Injury eCQM (CBE #4120e) and (2) the Hospital Harm—Postoperative Respiratory Failure eCQM (CBE #4130e). We are also proposing to modify the Global Malnutrition Composite Score eCQM (CBE #3592e) in the Medicare Promoting Interoperability Program measure set beginning with the CY 2026 reporting period, adding patients ages 18 to 64 to the current cohort of patients 65 years or older. A full description of this proposed change can be found in section IX.F.2 of the preamble of this proposed rule, including where interested parties can find the measure specification and other supporting information, which applies equally to support this proposal for the Medicare Promoting Interoperability Program.

We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections IX.C.5.c and IX.C.5.d of the preamble of this proposed rule for more information about these three measures, and our policy reasons for proposing them for adoption and modification. We propose to adopt the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM for the reasons stated in sections IX.C.5.c and IX.C.5.d of the preamble of this proposed rule. We propose to modify the Global Malnutrition Composite Score eCQM for the reasons stated in section IX.C. of the preamble of this proposed rule. Table IX.F.–07 and Table IX.F.–08 in the preamble of this proposed rule summarize previously finalized, newly proposed, and a proposed modification to eCQMs in the Medicare Promoting Interoperability Program for the CY 2026 reporting period, the CY 2027 reporting period, and subsequent years.

TABLE IX.F.-07: PREVIOUSLY FINALIZED AND PROPOSED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2026 REPORTING PERIOD

Short Name	Measure Name	CBE #
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm – Severe Hypoglycemia	3503e
HH-HYPER	Hospital Harm – Severe Hyperglycemia	3533e
HH-OREA	Hospital Harm – Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm – Pressure Injury	3498e
HH-AKI	Hospital Harm – Acute Kidney Injury	3713e
HH-FI*	Hospital Harm – Falls with Injury	4120e
HH-RF**	Hospital Harm – Postoperative Respiratory Failure	4130e
GMCS ***	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level – Inpatient)	3663e

* In this proposed rule, we are proposing adoption of the Hospital Harm – Falls with Injury eCQM beginning with the CY 2026 reporting period. We refer readers to section IX.C. of the preamble of this proposed rule for more detailed discussion.

** In this proposed rule, we are proposing adoption of the Hospital Harm – Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period. We refer readers to section IX.C. of the preamble of this proposed rule for more detailed discussion.

*** In this proposed rule, we are proposing modification to the Global Malnutrition Composite Score (GMCS) measure beginning with the CY 2026 reporting period. We refer readers to section IX.C. of the preamble of this proposed rule for more detailed discussion..

TABLE IX.F.-08: PREVIOUSLY FINALIZED AND PROPOSED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2027 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	CBE #
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-HYPO	Hospital Harm – Severe Hypoglycemia	3503e
HH-HYPER	Hospital Harm – Severe Hyperglycemia	3533e
HH-OREA	Hospital Harm – Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm – Pressure Injury	3498e
HH-AKI	Hospital Harm – Acute Kidney Injury	3713e
HH-FI*	Hospital Harm – Falls with Injury	4120e
HH-RF**	Hospital Harm – Postoperative Respiratory Failure	4130e
GMCS ***	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level – Inpatient)	3663e

* In this proposed rule, we are proposing adoption of the Hospital Harm – Falls with Injury eCQM beginning with the CY 2026 reporting period. We refer readers to section IX.C.5.c. of the preamble of this proposed rule for more detailed discussion.

** In this proposed rule, we are proposing adoption of the Hospital Harm – Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period. We refer readers to section IX.C.5.d. of the preamble of this proposed rule for more detailed discussion.

*** In this proposed rule, we are proposing modification to the Global Malnutrition Composite Score measure beginning with the CY 2026 reporting period. We refer readers to section IX.C.5.b. of the preamble of this proposed rule for more detailed discussion

We invite public comment on our proposals to adopt (1) the Hospital Harm—Falls with Injury eCQM (CBE #4120e) and (2) the Hospital Harm—Postoperative Respiratory Failure eCQM (CBE #4130e) to the measure set from which eligible hospitals and CAHs could self-select to report, and to modify the Global Malnutrition Composite Score eCQM (CBE #3592e), in the Medicare Promoting Interoperability Program for the CY 2026 and CY 2027 reporting periods, respectively, and subsequent years.

b. Proposal To Revise the eCQM Reporting and Submission Requirements for the CY 2026 Reporting Period and Subsequent Years

Consistent with our goal to align the eCQM reporting periods and criteria in the Medicare Promoting Interoperability Program with the Hospital IQR Program, eligible hospitals and CAHs are currently required to report four calendar quarters of data for each required eCQM: (1) the Safe Use of Opioids—Concurrent Prescribing eCQM; (2) the Severe Obstetric Complications eCQM; (3) the Cesarean Birth eCQM; and (4) three self-selected eCQMs, for the CY 2024 reporting period and subsequent years (87 FR 49365 through 49367).

In alignment with the Hospital IQR Program, we are proposing that, if our proposals to adopt the Hospital Harm—Falls with Injury eCQM and the Hospital Harm—Postoperative Respiratory Failure eCQM as detailed in sections IX.C and IX.F of the preamble of this proposed rule are finalized, these measures would be available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2026 reporting period and subsequent years.

We are also proposing to add the Hospital Harm—Severe Hypoglycemia eCQM, the Hospital Harm—Severe Hyperglycemia eCQM, and the Hospital Harm—Opioid-Related Adverse Events eCQM to the mandatory eCQM measure set for eligible hospitals and CAHs for the CY 2026 reporting period and subsequent years, bringing the total number of required eCQMs to nine for the CY 2026 reporting period. In summary, we are proposing that eligible hospitals and CAHs under the Medicare Promoting Interoperability Program would be required to report four calendar quarters of data for each of the following: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the Severe Obstetric Complications eCQM; (4) the Cesarean Birth eCQM; (5) the Hospital Harm—Severe Hypoglycemia eCQM; (6) the Hospital Harm—Severe Hyperglycemia eCQM; and (7) the

Hospital Harm—Opioid-Related Adverse Events eCQM, for a total of nine eCQMs, beginning with the CY 2026 reporting period.

In addition, we are proposing to add the Hospital Harm—Pressure Injury eCQM and the Hospital Harm—Acute Kidney Injury eCQM to the mandatory eCQM measure set for eligible hospitals and CAHs beginning with the CY 2027 reporting period and subsequent years. In summary, we are proposing that eligible hospitals and CAHs under the Medicare Promoting Interoperability Program would be required to report four calendar quarters of data for each of the following: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the Severe Obstetric Complications eCQM; (4) the Cesarean Birth eCQM; (5) the Hospital Harm—Severe Hypoglycemia eCQM; (6) the Hospital Harm—Severe Hyperglycemia eCQM; (7) the Hospital Harm—Opioid-Related Adverse Events eCQM; (8) the Hospital Harm—Pressure Injury eCQM; and (9) the Hospital Harm—Acute Kidney Injury eCQM, for a total of eleven eCQMs, beginning with the CY 2027 reporting period and subsequent years.

We refer readers to the discussion of the same proposals for the Hospital IQR Program in sections [IX.C.5.c.] and [IX.C.5.d.] of the preamble of this proposed rule for more information about the eCQM reporting and submission requirements, and our policy reasons for proposing these changes, which apply equally to support these proposals for the Medicare Promoting Interoperability Program.

We invite public comment on our proposals to increase the number of mandatory eCQM measures to a total of nine beginning with the CY 2026 reporting period, and to increase the number of mandatory eCQM measure to a total of eleven beginning with the CY 2027 reporting period and subsequent years.

7. Potential Future Update of the SAFER Guides Measure

a. Background

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45479 through 45481), we adopted the SAFER Guides measure under the Protect Patient Health Information objective beginning with the EHR reporting period in CY 2022. Eligible hospitals and CAHs are required to attest to whether they have conducted an annual self-assessment using all nine SAFER Guides,[542] at any point during the calendar year in which the EHR reporting period occurs, with one ''yes/no'' attestation statement. Beginning in CY 2022, the reporting of this measure was required, but eligible hospitals and CAHs were not scored, and an attestation of ''yes'' or ''no'' were both acceptable answers without penalty. For additional information, please refer to the discussion of the SAFER Guides measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45479 through 45481). In the FY 2024 IPPS/LTCH PPS final rule, we finalized a proposal to modify our requirement for the SAFER Guides measure beginning with the EHR reporting period in CY 2024 and continuing in subsequent years, to require eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment using all nine SAFER Guides, at any point during the calendar year in which the EHR reporting period occurs to be considered a meaningful user (88 FR 59262).

b. Status of Updates to SAFER Guides

We received comments in the FY 2024 IPPS/LTCH PPS proposed rule recommending that we work with ONC to update the SAFER Guides, citing that the SAFER Guides were last updated in 2016 (88 FR 59264). In response to these comments, we noted that, while the current SAFER Guides reflect relevant and valuable guidelines for safe practices with respect to current EHR systems, we would consider exploring updates in collaboration with ONC. We reminded readers to visit the CMS resource library website at *https://www.cms.gov/regulations-guidance/promoting-interoperability/resource-library* and the ONC website at *https://www.healthit.gov/topic/safety/safer-guides* for resources on the content and appropriate use of the SAFER Guides (88 FR 59262). We also noted that future updates to the SAFER Guides would be provided with accompanying educational and promotional materials to notify participants, in collaboration with ONC, when available (88 FR 59265). In this proposed rule, we are seeking to make readers aware that efforts to update the SAFER Guides are currently underway. We anticipate that updated versions of the SAFER Guides may become available as early as CY 2025, and we would consider proposing a change to the SAFER Guides measure for the EHR reporting period beginning in CY 2026 to permit use of an updated version of the SAFER Guides at that time. We encourage eligible hospitals and CAHs to become familiar with the updated versions of the SAFER Guides when they become available and consider them as they implement appropriate EHR safety practices.

8. Proposal To Update the Definition of Meaningful EHR User for Healthcare Providers That Have Committed Information Blocking

The Department of Health and Human Services (HHS) proposed rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the Disincentives proposed rule) (88 FR 74947), appeared in the **Federal Register** on November 1, 2023. If finalized, the final rule would implement the provision of the 21st Century Cures Act specifying that a healthcare provider, determined by the HHS Office of the Inspector General (OIG) to have committed information blocking, shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In the Disincentives proposed rule, we proposed that an eligible hospital or CAH would not be considered a meaningful EHR user in an EHR reporting period if the OIG refers, during the calendar year of the reporting period, a determination that the eligible hospital or CAH committed information blocking as defined at 45 CFR 171.103 (88 FR 74968). Furthermore, we proposed to revise the definition of ''Meaningful EHR User'' in 42 CFR 495.4 to state that an eligible hospital or CAH is not a meaningful EHR user in a payment adjustment year if the OIG refers a determination that the eligible hospital or CAH committed information blocking, as defined at 45 CFR 171.103, during the calendar year of the EHR reporting period (88 FR 74968 through 74969). Based upon the proposed revisions to 42 CFR 495.4, the downward payment adjustment would apply 2 years after the year of the referral and the EHR reporting period in which the eligible hospital was not a meaningful EHR user. For CAHs, the downward payment adjustment would apply to the payment adjustment year in which the OIG referral was made (88 FR 74957).

If the Disincentives proposed rule is finalized, an eligible hospital subject to this disincentive would be subject to a three quarters reduction of the annual market basket increase, while a CAH subject to this disincentive would have its payment reduced to 100 percent of reasonable costs, from the 101 percent of reasonable costs it might have otherwise earned, for failing to qualify as a meaningful EHR user in an applicable year. Additional regulatory

[542] *https://www.healthit.gov/topic/safety/safer-guides.*

provisions have been proposed at 45 CFR 171 Subpart J, related to the disincentives application process (88 FR 74953).

We note if the Disincentives proposed rule is finalized as proposed, the revised definition of Meaningful EHR User in 42 CFR 495.4 would become effective when the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule takes effect. For additional background and information on this proposed update, we refer readers to the discussion in the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking proposed rule on this topic (88 FR 74955 through 74957).

9. Future Goals of the Medicare Promoting Interoperability Program

a. Future Goals With Respect to Fast Healthcare Interoperability Resources® (FHIR) APIs for Patient Access

In partnership with ONC, we envision a future where patients have timely, secure, and easy access to their health information through the health application of their choice. We are working with ONC to enable this type of access to health information by requiring the use of APIs that utilize the Health Level Seven International® (HL7) FHIR. We work with ONC and other federal partners to improve timely and accurate data exchange, partner with industry to enhance digital capabilities, advance adoption of FHIR, support enterprise transformation efforts that increase our technological capabilities, and promote interoperability. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32858), we described our future vision for the Medicare Promoting Interoperability Program and stated that we will continue to consider changes that support a variety of HHS goals, including supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. We also solicited public comment on issues relevant to the Medicare Promoting Interoperability Program that related to policies finalized in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, including finalization of a new certification criterion for a standards-based API using FHIR, among other health IT topics (85 FR 32858).

ONC finalized the HTI–1 final rule (89 FR 1192), effective March 11, 2024, to further implement the 21st Century Cures Act, among other policy goals. ONC finalized revisions to the ''standardized API for patient and population services'' certification criterion at 45 CFR 170.315(g)(10). It also adopted the HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use version 6.1.0 at 45 CFR 170.215(b)(1)(ii), which provides the latest consensus-based capabilities aligned with the USCDI version 3 [543] data elements for FHIR APIs. The HTI–1 final rule also created the Insights Condition and Maintenance of Certification requirements (Insights Condition) within the ONC Health IT Certification Program to provide transparent reporting on certified health IT (89 FR 1199). This Insights Condition will require developers of certified health IT subject to the requirements to report on measures that provide information about the use of specific certified health IT functionalities by end users. One such measure calculates the number of unique individuals who access their electronic health information overall and by different methods such as through a standardized API for patient and population services.

By adopting these new and updated standards, implementation specifications, certification criteria, and conditions of certification, provisions in the HTI–1 final rule advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. CMS aims to further advance the use of FHIR APIs through policies in the Medicare Promoting Interoperability Program to advance interoperability, encourage the exchange of health information, and promote innovative uses of health IT. We also hope to gain insights into the adoption and use of FHIR APIs by eligible hospitals and CAHs due to the ONC Health IT Certification Program Insights Condition. We believe maintaining our focus on promoting interoperability, alignment, and simplification would reduce healthcare provider burden while allowing flexibility to pursue innovative applications that improve care delivery. For additional background and information, we refer readers to the discussion in the ONC HTI–1 final rule on this topic (89 FR 1192).

b. Improving Cybersecurity Practices

The Medicare Promoting Interoperability Program encourages the advancement of patient safety by promoting appropriate cybersecurity practices through the Security Risk Analysis and SAFER Guides measures. On February 14, 2023, the National Institute of Standards and Technology (NIST) published updated guidance for health care entities implementing requirements of the Health Insurance Portability and Accountability (HIPAA) Security Rule (45 CFR *Part 160* and Subparts A and C of *Part 164*; see also, most recently, 75 FR 40868 and 78 FR 5566). The guidance, NIST SP 800–66r2, provides information and resources to HIPAA-covered entities to improve their cybersecurity risk practices.[544] We also wish to alert readers of additional HHS resources and activities regarding cybersecurity best practices as recently summarized in an HHS strategy document that provides an overview of HHS recommendations to help the health care sector address cyber threats.[545] HHS has also recently published a website detailing recommended cybersecurity performance goals.[546] We intend to consider how the Medicare Promoting Interoperability Program can promote cybersecurity best practices for eligible hospitals and CAHs in the future.

c. Improving Prior Authorization Processes

We recently released the CMS Interoperability and Prior Authorization final rule (CMS–0057–F), which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758). This final rule aims to enhance health information exchange and access to health records for patients, healthcare providers, and payers, and improve prior authorization processes. In the final rule, we finalized the ''Electronic Prior Authorization'' measure under the HIE objective of the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category and under the HIE objective of the Medicare Promoting Interoperability Program, beginning, for the Medicare Promoting Interoperability Program, in the EHR reporting period in CY 2027 (89 FR 8909 through 8927).

10. Request for Information Regarding Public Health Reporting and Data Exchange

a. Background

The COVID–19 public health emergency (PHE) highlighted the interdependencies of public health and

[543] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3.*

[544] *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

[545] *https://aspr.hhs.gov/cyber/Documents/Health-Care-Sector-Cybersecurity-Dec2023-508.pdf.*

[546] *https://hphcyber.hhs.gov/performance-goals.html.*

healthcare, and the importance of timely, integrated, and interoperable data exchange across the health ecosystem to protect the health and safety of patients, populations, and the broader public. It also called attention to the distance between where we are as a nation and where we want to be with the interoperability of data between healthcare providers and PHAs, especially in the event of a fast-evolving pandemic or other type of PHE. While many jurisdictions were able to demonstrate the advantages of capabilities such as electronic laboratory reporting for reportable conditions, surveillance systems to support case investigations, immunization registries to track COVID–19 immunizations, and syndromic surveillance data for situational awareness, exchange across jurisdictions, and with some healthcare partners, remains inconsistent and, in some cases, burdensome.

The Medicare Promoting Interoperability Program plays an important role in advancing the exchange of health information between PHAs and eligible hospitals and CAHs, using certified Health IT Modules that meet criteria and standards established under the ONC Health IT Certification Program. Measures under the Public Health and Clinical Data Exchange objective focus on a key set of exchange capabilities for healthcare providers that have evolved over time to incorporate new priorities and technical approaches. In recent years, we have also focused on expanding and strengthening the Public Health and Clinical Data Exchange objective to further support the exchange of data that ultimately supports better patient and public health outcomes.

Efforts across HHS to advance the public health information infrastructure offer opportunities to further evolve the Medicare Promoting Interoperability Program. In 2020, the CDC launched the Data Modernization Initiative (DMI),[547] a multi-year, billion-plus dollar public health ecosystem initiative aimed at moving the public health community from a siloed and static public health data system to connected, resilient, adaptable, and sustainable 'response-ready' systems capable of meeting present and future health challenges. The DMI seeks to answer the need for a longer-term, whole-of-public health strategy that prioritizes collaboration and continuous improvement and recognizes that modernization is not a one-time event. To establish clear near-term priorities and milestones that complement the DMI's longer term focus and improve alignment of data modernization efforts at all levels of public health and across partners, CDC released its first Public Health Data Strategy (Ph.D.S) in 2023.[548] The Ph.D.S outlines the data, technology, policy, and administrative actions essential to exchange critical core data efficiently and securely across healthcare and public health.

In tandem with these efforts to chart a new strategic direction for improvements to the nation's public health infrastructure, evolving technical approaches are offering opportunities to automate and expand information exchange between healthcare providers and PHAs. ONC is exploring updates to existing certification criteria for health IT that support current measures in the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange objective, new criteria that incorporate modern approaches to exchange, support additional types of information needed by PHAs, and criteria that focus on entities receiving public health data. In the HTI–1 final rule, ONC finalized updates to the health IT certification criterion for electronic case reporting in 45 CFR 170.315(f)(5), incorporating standards-based approaches to existing functional requirements in accordance with the HL7 FHIR Electronic Case Report (eCR) Implementation Guide (IG) or HL7 Clinical Document Architecture (CDA) Electronic Initial Case Report (eICR) IG (89 FR 1226). ONC is also considering recent recommendations from federal advisory committees that have focused on issues related to public health interoperability. These include the Public Health Data Systems Task Force, which was charged by the Health Information Technology Advisory Committee (HITAC) to inform ONC's continued collaborative work with CDC on improving public health data systems, and in support of CDC's greater DMI efforts. In November 2022, the Public Health Data Systems Task Force issued recommendations to the HITAC,[549] which included a focus on new criteria for Health IT Modules that support public health use cases that aim to standardize technology that receives information from healthcare providers. In addition, the CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup adopted a report on November 3, 2022, which addressed standards for public health data systems and implementing a certification program for public health IT, and other issues.[550] We are working in partnership with the CDC and ONC to explore how the Medicare Promoting Interoperability Program could advance public health infrastructure through more advanced use of health IT and data exchange standards. This Request for Information (RFI) describes a series of goals and principles for the Medicare Promoting Interoperability Program's Public Health and Clinical Data Exchange objective, provides information about recommended updates to certified health IT under consideration that may impact eligible hospitals and CAHs, and seeks public comment on potential updates to the program that could help achieve these goals.

b. Goals for Public Health Reporting

As we look toward the future of the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program, we believe decision-making and prioritization about policy change should adhere to four goals:

- The meaningful use of CEHRT enables continuous improvement in the quality, timeliness, and completeness of public health data being reported.
- The meaningful use of CEHRT allows for flexibility to respond to new public health threats and meet new data needs without requiring new and substantial regulatory and technical development.
- The meaningful use of CEHRT supports mutual data sharing between public health and healthcare providers.
- Reporting burden on eligible hospitals and CAHs is significantly reduced.

These goals inform the questions provided at the end of this RFI. We invite public comment on these four goals.

c. Public Health in the ONC Health IT Certification Program

We continue to collaborate closely with ONC on policy changes in the ONC Health IT Certification Program that either impact existing functionality reflected in the Medicare Promoting Interoperability Program measures or represent new capabilities for eligible

[547] *https://www.cdc.gov/surveillance/data-modernization/index.html.*

[548] *https://www.cdc.gov/ophdst/public-health-data-strategy/index.html.*

[549] See ''Final Report of the Health Information Technology Advisory Committee on Public Health Data Systems'' *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

[550] See ''Data and Surveillance Workgroup Report,'' CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW). *https://www.cdc.gov/about/pdf/advisory/dsw-recommendations-report.pdf.*

hospitals and CAHs that could offer opportunities to achieve our goals for the Public Health and Clinical Data Exchange objective. In this section we describe recommended updates to health IT certification criteria.

(1) Making Available New Capabilities for Exchanging Data With PHAs Using the FHIR Standard

Current public health related certification criteria at 45 CFR 170.315(f)(1) through (7) generally reference HL7 version 2 and CDA standards that support single-patient, event-based submission of data from healthcare providers to PHAs, such as electronic transmission of laboratory results (HL7® Version 2.5.1 Implementation Guide for Electronic Laboratory Reporting to Public Health, Release 1 with Errata and Clarifications) or electronic initial case reports (HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2) to public health agencies. However, these standards may not adequately support more complex data exchange use cases, such as bulk exchange of data for patients who received a specific vaccine. Approaches using FHIR could more effectively support a wide-scale public health response and reduce burden of implementation and maintenance for data exchange between and among healthcare providers and PHAs.

Increased availability of FHIR-based APIs across systems used by PHAs and healthcare providers could help to create an ecosystem where PHAs could use health IT to securely query data directly from the source, in real time, based on an initial push of relevant data, when needed. Availability of a FHIR API in a healthcare provider's certified health IT could enable a PHA to query an eligible hospital or CAH's CEHRT for data on any patient with a specific condition when needed, avoiding the need for the eligible hospital or CAH to take additional action to submit additional information.

As noted, ONC has already finalized an update to the electronic case reporting criterion in 45 CFR 170.315(f)(5), which provides an option to implement the HL7 FHIR eCR IG as part of a Health IT Module certified to the criterion (89 FR 1226). The Public Health Data Systems Task Force report stated that ''FHIR-based query may offer public health additional avenues to meet the needs of case investigation to supplement electronic case reporting and emerging public health threats'' and that ''FHIR may support a more focused and relevant response by providers to meet public health queries.'' [551]

While FHIR specifications are not available for all the use cases currently supported in the public health criteria at 45 CFR 170.315(f)(1)–(7), ONC continues to evaluate standards development activities around the use of FHIR for public health data exchange that could be incorporated into existing or new certification criteria, such as replacing HL7 version 2 and CDA exchange specifications with a FHIR approach over time.

(2) Expanding the Scope of Public Health Exchange Supported by Certified Health IT Capabilities

Existing health IT certification criteria are linked to measures under the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, covering use cases from transmission to immunization registries and syndromic surveillance, to reportable laboratory test values/results and eCR.

The Public Health Data Systems Task Force report recommended the addition of several additional certification criteria reflecting exchange of information such as birth and death data, the results of newborn screening services, and situational awareness.[552] ONC is monitoring these and other areas of importance to public health that are not reflected in the current certification criteria.

(3) Introducing Certification Criteria for Systems That Receive Public Health Data

To date, ONC health IT certification criteria have been designed with systems that send data to PHAs in mind, particularly health IT systems used by healthcare providers, that exchange data with PHAs. Misalignment between certified health IT products and technology and systems used by PHA, has created challenges for both healthcare providers and PHAs, including reliance on complex workflows to accommodate non-harmonized and variable data elements and exchange standards. Inefficiencies associated with workarounds and custom processes can lead to further reductions in data quality, completeness, consistency, and interoperability.

The HITAC Public Health Data Systems Task Force's report includes a recommendation ''that ONC establish certification criteria for public health technologies used by Public Health Authorities in support of their responsibilities in exchanging data for public health purposes including those defined in the existing (f) criteria.'' [553]

By establishing minimum functional capabilities and exchange standards to both send and receive public health data, health IT certification criteria could enhance interoperability across healthcare providers and PHAs and provide a long-term mechanism for alignment as data exchange matures over time. An expansion of the ONC Health IT Certification Program to focus on the receiving side could also bolster CDC's public health infrastructure modernization efforts described above, by helping PHAs align with health care provider data sources using the same certification criteria and standards, and enabling entities to move together on a common timeline for updating technology requirements.

d. RFI Questions

(1) Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting

The Medicare Promoting Interoperability Program's requirement that eligible hospitals and CAHs report their level of ''active engagement'' between the eligible hospital or CAH, and a PHA, as well as the recently established one-year limitation in how long an eligible hospital or CAH may spend in Pre-Production and Validation, has provided a basis that could broadly incentivize the exchange of EHR data (87 FR 49339 through 49340). However, because active engagement reporting only requires an attestation of whether an eligible hospital or CAH is reporting production data or still in the process of validation, this approach does not allow us to assess eligible hospitals and CAHs on the comprehensiveness, quality, or timeliness of the data they provide to PHAs. We are considering whether alternatives to the ''active engagement'' approach could better allow us to assess eligible hospital and CAH performance, meet the data needs of PHAs, and ultimately allow us to incentivize increased performance in these areas. We are interested in how we could

[551] Public Health Data Systems Task Force, Recommendation 23, p. 11 *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

[552] Public Health Data Systems Task Force, Recommendation 18–21, p. 10–11 *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

[553] Public Health Data Systems Task Force, Recommendation 1, p. 7. *https://www.healthit.gov/sites/default/files/page/2022-11/2022-11-10_PHDS_TF_Recommendations_Report_Transmittal_Letter_508.pdf.*

think about alternatives to the ''active engagement'' approach described above. We are also interested in the increasing focus on leveraging FHIR-based data exchange for public health needs. Finally, we are interested in ensuring that any changes to the active engagement approach are implemented in a way that takes advantage of opportunities to further automate reporting and minimize administrative burden for eligible hospitals and CAHs. Therefore, we are seeking public comment and feedback on the questions and topic areas listed:

- Today, the measures in the Public Health and Clinical Data Exchange objective assess whether there is active engagement between an eligible hospital or CAH and a PHA, but do not measure the level of performance the eligible hospital or CAH has achieved in sending information. Specifically, we are seeking public comment on the following questions:

++ Should CMS shift to numerator/denominator reporting requirements for current and future measures in the Public Health and Clinical Data Exchange objective? If so, should CMS prioritize only certain measures for numerator/denominator reporting?

++ New technical approaches such as the use of FHIR APIs to support information exchange with PHAs could enable PHAs to query healthcare provider systems directly, after an initial trigger, rather than solely relying on a healthcare provider to take action to share information. How could performance be measured under approaches such as the use of FHIR APIs to support information exchange with PHAs? Would numerator/denominator reporting be appropriate under such approaches?

- Continued expansion of the measures under the Public Health and Clinical Data Exchange objective to address different reporting use cases can incentivize eligible hospitals and CAHs to make more comprehensive information available to PHAs. We are seeking public comment on the following questions:

++ Should CMS continue to add measures under the Public Health and Clinical Data Exchange objective to include additional system-specific requirements (for example, vital records)? If so, which ones and why?

++ Should CMS create a new measure for each new type of data or use case added to the Public Health and Clinical Data Exchange objective? What are the risks of including too many measures under the objective?

++ Alternatively, should CMS explore ways to group data types and use cases under a more limited set of Public Health and Clinical Data Exchange objective measures?

—Anecdotal reports suggest that some healthcare providers are attesting to active engagement with public health for the ''Electronic Case Reporting'' measure if they report cases for at least one notifiable condition (for example, COVID–19).

++ How can CMS incentivize more complete electronic case reporting to PHAs? For example, should CMS update the measure to require healthcare providers to meet a certain threshold for conditions reported?

++ What potential benefit versus burden trade-offs CMS should consider? How should CMS account for varying levels of public health readiness and capacity for expanding conditions reported electronically, such as in rural areas?

++ What additional levers besides the Medicare Promoting Interoperability Program should CMS explore to improve the completeness of reporting to public health? How should CMS work with other partners to incentivize or require reporting?

(2) Questions for Goal #2, Flexibility and Adaptability of the Public Health Reporting Enterprise

During the COVID–19 and Mpox PHEs, healthcare providers and PHAs often had to quickly update their systems to report case, laboratory, and vaccination data related to these novel pathogens and interventions devised in response to them. In this section, we are seeking information about how the Medicare Promoting Interoperability Program could improve the ability for public health infrastructure [554] to quickly adapt to new threats. Specifically, we are seeking public comment on the following questions:

- How can the Medicare Promoting Interoperability Program support or incentivize response ready reporting capabilities for healthcare providers? What, if any, challenges exist around sharing data with PHAs?
- How can CMS and ONC work with vendors to ensure that provider systems are being continually updated to meet new data needs, such as those in rural areas?

(3) Questions for Goal #3, Increasing Bi-Directional Exchange With Public Health Agencies

The transition to, and use of, more modern, flexible approaches and networks that support data exchange between and across public health and healthcare is a key goal of HHS efforts to modernize the public health information infrastructure. We are interested in ways that the Medicare Promoting Interoperability Program can support this transition. Specifically, we are seeking public comment on the following questions:

- Both CDC's ACD and ONC's HITAC have recommended that CDC and ONC work together to establish certification criteria for public health technologies used by PHAs and implement a coordinated, phased approach to incentivize and eventually require their adoption.[555] How, if at all, could the Medicare Promoting Interoperability Program support or incentivize PHA adoption of certified systems and technologies?
- How can CMS use the Public Health and Clinical Data Exchange objective to incentivize early adoption of FHIR-based APIs for public health data exchange?
- CMS previously finalized the Enabling Exchange under TEFCA measure under the HIE objective for eligible hospitals and CAHs to attest to engaging in health information exchange. Should CMS introduce a similar measure to allow providers to receive credit for the HIE objective by exchanging public health data through participation in TEFCA?

(4) Questions for Goal #4, Eliminating Reporting Burden for Healthcare Providers

We are committed to continuing to reduce reporting burden for healthcare providers, such as in rural areas, as part of any updates to the Medicare Promoting Interoperability Program undertaken to support the priorities described above. Specifically, we are seeking public comment on the following questions:

- Under the current Public Health and Clinical Data Exchange objective, which measures, or other requirements result in the most administrative burden for eligible hospitals and CAHs?
- How can the Medicare Promoting Interoperability Program balance robust Public Health and Clinical Data Exchange objective requirements with our desire to reduce burden on eligible hospitals and CAHs?
- How can new technical approaches to data exchange with PHAs, such as the use of FHIR APIs, reduce burden for health care providers? What are potential barriers to achieving burden

[554] *https://www.cdc.gov/infrastructure/pdfs/PHIC-Overview.pdf.*

[555] *https://www.healthit.gov/sites/default/files/page/2023-03/2023-02-08_HITAC_Annual_Report_for_FY22_508_1.pdf.*

reduction as these new approaches are implemented?

X. Other Provisions Included in This Proposed Rule

A. Proposed Transforming Episode Accountability Model (TEAM)

1. General Provisions

a. Introduction

The CMS Innovation Center has designed and tested numerous alternative payment models that each include specific payment, quality, and other policies. However, there are some general provisions that are very similar across models. The general provisions address beneficiary protections, model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review, and miscellaneous provisions on bankruptcy and other notifications.

We propose to implement the general provisions, described later in this section and in subpart E of this part 512, based on similar requirements that have been previously finalized in existing model tests. In addition to the general provisions discussed here, TEAM-specific provisions that are uniquely tailored to this model are described elsewhere in this rule.

b. Basis and Scope

In § 512.500, we propose that the proposed general provisions in this section X.A.1. of the preamble of this proposed rule would only be applicable to TEAM. These proposed general provisions would not, except as specifically noted in proposed part 512, subpart E, affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity (such as those in parts 413, 414, 419, 420, and 489 of chapter IV of 42 CFR and those in parts 1001 through 1003 of chapter V of 42 CFR).

We invite public comment on the proposed general provisions discussed in this section of the proposed rule.

c. Definitions

We propose at § 512.505 to define certain terms relevant to the general provisions proposed in this section X.A.1. of the preamble of this proposed rule. We are proposing to define the term ''TEAM participant'' to mean an acute care hospital that is identified as a TEAM participant under the terms of and defined in proposed § 512.505. We propose to define ''downstream participant'' to mean an individual or entity that has entered into a written arrangement with a TEAM participant pursuant to which the downstream participant engages in one or more TEAM activities. A downstream participant may include, but would not be limited to, an individual practitioner, as defined for purposes of TEAM. We propose to define ''TEAM activities'' to mean any activities impacting the care of model beneficiaries related to the test of TEAM performed under the terms of proposed 512 subpart E.

We describe additional proposed definitions in context throughout this section X.A.1. of the preamble of this proposed rule.

d. Cooperation With Model Evaluation and Monitoring

Section 1115A(b)(4) of the Act requires the Secretary to evaluate each model tested under the authority of section 1115A of the Act and to publicly report the evaluation results in a timely manner. The evaluation must include an analysis of the quality of care furnished under the model and the changes in program spending that occurred due to the model. Models tested by the CMS Innovation Center are rigorously evaluated. For example, when evaluating models tested under section 1115A of the Act, we require the production of information that is representative of a wide and diverse group of model participants and includes data regarding potential unintended or undesirable effects, such as cost-shifting. The Secretary must take the evaluation into account if making any determinations regarding the expansion of a model under section 1115A(c) of the Act.

In addition to model evaluations, the CMS Innovation Center regularly monitors model participants for compliance with model requirements. For the reasons described in section X.A.1. of the preamble of this proposed rule, these compliance monitoring activities are an important and necessary part of the model test.

Therefore, we are proposing to codify at § 512.584, that TEAM participants and their downstream participants must comply with the requirements of 42 CFR 403.1110(b) (regarding the obligation of entities participating in the testing of a model under section 1115A of the Act to report information necessary to monitor and evaluate the model), and must otherwise cooperate with CMS' model evaluation and monitoring activities as may be necessary to enable CMS to evaluate TEAM in accordance with section 1115A(b)(4) of the Act. This participation in the evaluation may include, but is not limited to, responding to surveys and participating in focus groups. Additional details on the specific research questions that we propose that the TEAM evaluation will consider can be found in section X.A.3.o. of the preamble of this proposed rule. Further, we propose to conduct monitoring activities according to proposed § 512.590(b), described in section X.A.3.i. of the preamble of this proposed rule, including producing such data as may be required by CMS to evaluate or monitor TEAM, which may include protected health information as defined in 45 CFR 160.103 and other individually identifiable data.

e. Rights in Data and Intellectual Property

To enable CMS to evaluate TEAM as required by section 1115A(b)(4) of the Act and to monitor TEAM pursuant to § 512.590, described at section X.A.3.i. of the preamble of this proposed rule, we are proposing to allow CMS to use any data obtained in accordance with proposed § 512.588 to evaluate and monitor the proposed TEAM. We further propose that, consistent with section 1115A(b)(4)(B) of the Act, that CMS would be allowed to disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. We propose that the data to be disseminated would include, but would not be limited to, patient de-identified results of patient experience of care and quality of life surveys, as well as patient de-identified measure results calculated based upon claims, medical records, and other data sources.

In order to protect the intellectual property rights of TEAM participants and downstream participants, we propose in § 512.588(c) to TEAM participants and their downstream participants to label data they believe is proprietary and should be protected from disclosure under the Trade Secrets Act. We would note that this approach is already in use in other models currently being tested by the CMS Innovation Center, including the Radiation Oncology and End Stage Renal Disease Treatment Choices models. Any such assertions would be subject to review and confirmation prior to CMS's acting upon such assertion.

We further propose to protect such information from disclosure to the full extent permitted under applicable laws, including the Freedom of Information Act. Specifically, in proposed § 512.588(b), we propose to not release data that has been confirmed by CMS to

be proprietary trade secret information and technology of the TEAM participant or its downstream participants without the express written consent of the TEAM participant or its downstream participants, unless such release is required by law.

f. Remedial Action

As stated earlier in this proposed rule, as part of the CMS Innovation Center's monitoring and assessment of the impact of models tested under the authority of section 1115A of the Act, we have a special interest in ensuring that these model tests do not interfere with the program integrity interests of the Medicare program. For this reason, we monitor for compliance with model terms as well as other Medicare program rules. When we become aware of noncompliance with these requirements, it is necessary for CMS to have the ability to impose certain administrative remedial actions on a noncompliant model participant.

The terms of many models currently being tested by the CMS Innovation Center permit CMS to impose one or more administrative remedial actions to address noncompliance by a model participant. We propose that CMS may impose any of the remedial actions set forth in proposed § 512.592 if we determine that the TEAM participant or a downstream participant—

- Has failed to comply with any or all of the terms of TEAM, if finalized;
- Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
- Has taken any action that threatens the health or safety of a beneficiary or other patient;
- Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of TEAM;
- Has undergone a change in control (as defined in proposed § 512.505) that presents a program integrity risk;
- Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency;
- Is subject to investigation or action by HHS (including the HHS–OIG and CMS) or the Department of Justice due to an allegation of fraud, a pattern of improper billing, or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act qui tam matter in which the Federal Government has intervened, or similar action; or
- Has failed to demonstrate improved performance following any remedial action imposed by CMS.

In § 512.592(b), we propose to codify that CMS may take one or more of the following remedial actions if CMS determined that one or more of the grounds for remedial action described in proposed § 512.592(a) had taken place—

- Notify the TEAM participant and, if appropriate, require the TEAM participant to notify its downstream participants of the violation;
- Require the TEAM participant to provide additional information to CMS or its designees;
- Subject the TEAM participant to additional monitoring, auditing, or both;
- Prohibit the TEAM participant from distributing TEAM payments;
- Require the TEAM participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to TEAM;
- Terminate the TEAM participant from the model test;
- Require the TEAM participant to submit a corrective action plan in a form and manner and by a date specified by CMS;
- Discontinue the provision of data sharing and reports to the TEAM participant;
- Recoup TEAM payments;
- Reduce or eliminate a TEAM payment otherwise owed to the TEAM participant, as applicable; or
- Such other action as subpart E of part may be permitted under the terms of proposed 512.

We would note that because TEAM is a mandatory model, we would not expect to use the proposed provision that would allow CMS to terminate a TEAM participant's participation in the model, except in circumstances in which the TEAM participant has engaged, or is engaged in, egregious actions.

We invite public comment on these proposed provisions regarding the proposed grounds for remedial actions, remedial actions generally, and whether additional types of remedial action would be appropriate.

g. CMS Innovation Center Model Termination by CMS

We are proposing certain provisions that would allow CMS to terminate TEAM under certain circumstances. Section 1115A(b)(3)(B) of the Act requires the CMS Innovation Center to terminate or modify the design and implementation of a model, after testing has begun and before completion of the testing, unless the Secretary determines, and the Chief Actuary certifies with respect to program spending, that the model is expected to: improve the quality of care without increasing program spending; reduce program spending without reducing the quality of care; or improve the quality of care and reduce spending.

We propose at § 512.596 that CMS could terminate TEAM for reasons including, but not limited to, one of the following circumstances:

- CMS determines that it no longer has the funds to support TEAM.
- CMS terminates TEAM in accordance with section 1115A(b)(3)(B) of the Act.

As provided by section 1115A(d)(2)(E) of the Act and proposed § 512.596, termination of TEAM in accordance with section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

To ensure model participants had appropriate notice in the case of the termination of TEAM by CMS, we also propose to codify at § 512.596 that we would provide TEAM participants with written notice of the model termination, which would specify the grounds for termination as well as the effective date of the termination.

h. Limitations on Review

In proposed § 512.594, we propose to codify the preclusion of administrative and judicial review under section 1115A(d)(2) of the Act. Section 1115A(d)(2) of the Act states that there is no administrative or judicial review under section 1869 or 1878 of the Act or otherwise for any of the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites, or participants to test models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act.
- Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such section.

We propose to interpret the preclusion from administrative and judicial review regarding the CMS Innovation Center's selection of organizations, sites, or participants to test TEAM to preclude from administrative and judicial review our selection of a TEAM participant, as well as our decision to terminate TEAM

participant, as these determinations are part of our selection of participants for TEAM.

We invite public comment on the proposed codification of these statutory preclusions of administrative and judicial review for TEAM, as well as our proposed interpretations regarding their scope.

i. Miscellaneous Provisions on Bankruptcy and Other Notifications

The proposed TEAM would have a defined period of performance, but final payment under the model may occur long after the end of this performance period. In some cases, a TEAM participant could owe money to CMS. We recognize that the legal entity that is the TEAM participant could experience significant organizational or financial changes during or after the period of performance for TEAM. To protect the integrity of the proposed TEAM and Medicare funds, we are proposing a number of provisions to ensure that CMS is made aware of events that could affect a TEAM participant's ability to perform its obligations under TEAM, including the payment of any monies owed to CMS.

First, in proposed § 512.595(a), we propose that a TEAM participant must promptly notify CMS and the local U.S. Attorney Office if it files a bankruptcy petition, whether voluntary or involuntary. Because final payment may not take place until after the TEAM participant ceases active participation in TEAM, we further propose that this requirement would apply until final payment has been made by either CMS or TEAM participant under the terms of the model and all administrative or judicial review proceedings relating to any payments under TEAM has been fully and finally resolved.

Specifically, we propose that notice of the bankruptcy must be sent by certified mail within 5 days after the bankruptcy petition has been filed and that the notice must contain a copy of the filed bankruptcy petition (including its docket number), unless final payment has been made under the terms of TEAM and all administrative or judicial review proceedings regarding TEAM payments between the TEAM participant and CMS have been fully and finally resolved. The notice to CMS must be addressed to the CMS Office of Financial Management, Mailstop C3–01–24, 7500 Security Boulevard, Baltimore, Maryland 21244 or to such other address as may be specified for purposes of receiving such notices on the CMS website.

By requiring the submission of the filed bankruptcy petition, CMS would obtain information necessary to protect its interests, including the date on which the bankruptcy petition was filed and the identity of the court in which the bankruptcy petition was filed. We recognize that such notices may already be required by existing law, but CMS often does not receive them in a timely fashion, and they may not specifically identify TEAM. The failure to receive such notices on a timely basis can prevent CMS from asserting a claim in the bankruptcy case. We are particularly concerned that a TEAM participant may not furnish notice of bankruptcy after it has completed its performance in TEAM, but before final payment has been made or administrative or judicial proceedings have been resolved. We believe our proposal is necessary to protect the financial integrity of the proposed TEAM and the Medicare Trust Funds.

Second, in proposed § 512.595(b), we propose that the TEAM participant would have to provide written notice to CMS within 30 days of any change in the TEAM participant's legal name becoming effective. The notice of legal name change would have to be in a form and manner specified by CMS and include a copy of the legal document effecting the name change, which would have to be authenticated by the appropriate state official. The purpose of this proposed notice requirement is to ensure the accuracy of our records regarding the identity of TEAM participants and the entities to whom TEAM payments should be made or against whom payments should be demanded or recouped. We solicit comment on requiring notice to be furnished promptly, that is, within 30 days after a change in legal name has become effective.

Third, in proposed § 512.595(c), we propose that the TEAM participant would have to provide written notice to CMS at least 90 days before the effective date of any change in control. We propose that the written notification must be furnished in a form and manner specified by CMS. For purposes of this notice obligation, we propose that a ''change in control'' would mean any of the following: (1) The acquisition by any ''person'' (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the TEAM participant representing more than 50 percent of the TEAM participant's outstanding voting securities or rights to acquire such securities; (2) the acquisition of the TEAM participant by any individual or entity; (3) the sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the TEAM participant; or (4) the approval and completion of a plan of liquidation of the TEAM participant, or an agreement for the sale or liquidation of the TEAM participant. The proposed requirement and definition of change in control are the same requirements and definition used in certain models that are currently being tested under section 1115A authority. We believe this proposed notice requirement is necessary to ensure the accuracy of our records regarding the identity of model participants and to ensure that we pay and seek payment from the correct entity. For this reason, we propose that if CMS determined in accordance with proposed § 512.592(a)(5) that a TEAM participant's change in control would present a program integrity risk, CMS could take remedial action against the TEAM participant under proposed § 512.592(b). In addition, to ensure payment of amounts owed to CMS, we propose that CMS may require immediate reconciliation and payment of all monies owed to CMS by a model participant that is subject to a change in control.

We invite public comment on these proposed notification requirements.

2. Proposed Transforming Episode Accountability Model (TEAM)—Introduction

We are proposing the implementation and testing of the Transforming Episode Accountability Model (TEAM), a new mandatory alternative payment model under the authority of section 1115A of the Act, beginning on January 1, 2026, and ending on December 31, 2030. TEAM would test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories. Specifically, the proposed TEAM would test five surgical episode categories: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion.

Under the FFS program, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the

course of an episode. With the amount of payments dependent on the volume of services delivered, acute care hospitals may not have incentives to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. By holding acute care hospitals accountable for all items and services provided during an episode, acute care hospitals are better incentivized to coordinate patient care, avoid duplicative or unnecessary services, and improve the beneficiary care experience during care transitions.

This proposed model falls within a larger framework of activities initiated by the CMS Innovation Center during the past several years, including the release of the CMS Innovation Center strategic refresh and the comprehensive specialty strategy.[556] [557] The strategic refresh includes a goal of having 100 percent of Medicare FFS beneficiaries and the vast majority of Medicaid beneficiaries in an accountable care relationship by 2030. Episode-based payment models, such as TEAM, can be a tool to support this goal by increasing provider participation in value-based care initiatives with accountability for quality and cost outcomes. To further the goals of the strategic refresh, the CMS Innovation Center released the comprehensive specialty care strategy in 2022, which includes an element to maintain momentum established by episode-based payment models and supports development of TEAM.[558] In addition, in July 2023, we published a Request for Information (RFI) to gain public input on design elements for a new mandatory bundled payment model.[559] Given TEAM's alignment with many strategic facets of the CMS Innovation Center, our proposal to test a new episode-based payment model for acute care hospitals is based on: (1) lessons learned from testing the Bundled Payments for Care Improvement (BPCI) Initiative, the BPCI Advanced Model, and the Comprehensive Care for Joint Replacement (CJR) Model; and (2) comments received from the Episode-based Payment Model RFI (88 FR 45872) published in the **Federal Register**.

Under this proposed TEAM, TEAM participants continue to bill Medicare under the traditional FFS system for services furnished to Medicare FFS beneficiaries. However, the TEAM participant may also receive a reconciliation payment amount from CMS depending on their Composite Quality Score (CQS) and if their performance year spending is less than their reconciliation target price. As TEAM is a two-sided risk model, meaning the model requires TEAM participants to be accountable for performance year spending that is above or below their reconciliation target price, TEAM participants may also owe CMS a repayment amount depending on their CQS and if their performance year spending is more than their reconciliation target price.

The model performance period for the proposed TEAM would consist of five performance years, beginning January 1, 2026, and ending December 31, 2030, with final data submission of clinical data elements and quality measures in CY 2031 to account for episodes ending in CY 2030, and final reconciliation reports and TEAM reconciliation payment amounts and repayment amounts in CY 2031.

a. Background

CMS is seeking to improve beneficiary care by using an episode-based payment structure to align incentives in pursuit of improved quality and reduced spending. A FFS payment system pays health care providers and suppliers for discrete services over a single episode, potentially resulting in fragmented care and duplicative use of resources. Paying for discrete services may also not provide sufficient financial incentive for health care providers and suppliers to invest in quality improvement and care coordination that could help avoid adverse outcomes. Further, providers and suppliers may be paid under different FFS payment systems which may create challenges managing beneficiaries in an episode. Therefore, providers and suppliers have less of an incentive to collaborate to improve the quality of care and decrease the cost and unnecessary utilization of services.

An episode-based payment methodology creates an incentive for participating providers and suppliers to coordinate across care settings as the participating entity takes responsibility for the quality and cost outcomes across the entire episode. All of the projected payments to the physician, hospital, and other health care provider and supplier services are combined into a target price. This target price represents the expected cost of all items and services furnished to a beneficiary during an episode. Health care providers included in such initiatives may either realize a financial gain or loss, based on how successfully they perform on quality measure assessment and manage resources and total costs throughout each episode. Payment models that hold entities accountable for spending and quality performance metrics for an entire episode can motivate health care providers to furnish services more efficiently, to better coordinate care, and to improve the quality of care.

The CMS Innovation Center has tested episode-based payment models for over a decade, including the BPCI initiative, the BPCI Advanced Model, and the CJR Model. The CJR Model and the BPCI Advanced Models are current CMS Innovation Center model tests that are set to end on December 31, 2024, and December 31, 2025, respectively. When considering the future of episode-based payment models, we reviewed results of the CJR Model and the BPCI Advanced Model given promising evaluation findings that support these models reducing episode payments, before accounting for incentive payments, and maintaining quality of care, as described further in section X.A.2.c. of the preamble of this proposed rule. However, both models experienced significant model changes, including changes in participation volume, in the later years of their model test and assessing the results of these models based on their current methodologies requires additional evaluation data, which would not be available until after each model has concluded. We believe TEAM would allow the CMS Innovation Center to test a new episode-based payment model that builds upon lessons learned in previous episode-based payment models by incorporating the most promising model features, while also continuing care transformation efforts that we have promoted through the CJR or BPCI Advanced models.

If the proposed TEAM is successful, we hope this model would establish the framework for managing episodes as a standard practice in Traditional Medicare. The proposed TEAM includes features that are attentive to operational feasibility for both participants and CMS, such as how often reconciliation would be conducted to minimize administrative burden, a pricing methodology that would be responsive to providers with varying levels of experience and different patient populations, and the selection of episodes with sufficient volume that would warrant standard care pathways

[556] Innovation Center Strategy Refresh: *https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.*

[557] The CMS Innovation Center's Strategy to Support Person-centered, Value-based Specialty Care: *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

[558] *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care.*

[559] *https://www.federalregister.gov/documents/2023/07/18/2023-15169/request-for-information-episode-based-payment-model.*

during the acute and post-acute care periods of an episode. Any future policy changes to this proposed model test, such as the addition of episode categories, would be implemented through future notice and comment rulemaking.

Increasing quality, patient-centeredness, and cost-effective care requires collaboration among hospitals, physicians, and post-acute care (PAC) providers. To encourage this collaboration, TEAM proposes to further align incentives between hospitals and physicians by specifying certain types of financial arrangements that participants may elect to pursue to share reconciliation payment amounts received from CMS under the model. By doing so, TEAM participants would be able to share incentives with downstream providers and suppliers when they achieve higher quality and more cost-effective care through collaboration.

b. Evidence Base for Model Proposal

Medicare beneficiaries can experience fragmented and costly care, distinguished by frequent diagnostics, imaging, tests and other treatment approaches delivered by different providers across different sites of care.[560] A 2022 study examining fragmentation of ambulatory care for Medicare FFS beneficiaries found that four in ten beneficiaries experience highly fragmented care, with a mean of 13 ambulatory visits across seven practitioners in one year.[561] Fragmented care is further evident when focusing on the clinical management of Medicare beneficiaries for acute procedural care since these beneficiaries may be receiving care from different physicians in different settings before, during, and after their procedure.[562] In the absence of effective communication between patients, families, physicians, hospitals, and other care settings, beneficiaries receiving acute procedural care may not receive comprehensive care management and coordination. The proposed TEAM is based on the premise that appropriately aligned financial incentives would improve care coordination for beneficiaries who are in an episode, resulting in better health outcomes.

Care fragmentation in acute surgical procedures in the United States is well documented, leading to care variation and inefficiencies producing unfavorable patient outcomes and increased health spending.[563] [564] [565] Given the variation in acute surgical care and costs, including post-acute care costs immediately following a procedure, significant literature has been devoted to evaluating opportunities to improve the quality and efficiency of care.[566] [567] This includes the design and implementation of standardized care processes that emphasize high-value care that can support episode-based care initiatives. For example one study found that, ''Enhanced Recovery After Surgery protocols have resulted in shorter length of hospital stay by 30% to 50% and similar reductions in complications, while readmissions and costs are reduced''.[568] Moreover, other findings focus on perioperative care delivery and indicate, ''that through elements that emphasize care coordination, standardization, and patient-centeredness, perioperative surgical home programs can improve patient postoperative recovery outcomes and decrease hospital utilization''.[569]

CMS, commercial payers, and other stakeholders are continuously testing a variety of approaches to constructing episodes of care, including through different patient populations, clinical episode categories, and pricing methodologies.[570] [571] [572] Though the results of alternative payment models focused on episodes of care have been mixed, evidence related to models' ability to realize savings and improve quality is promising, especially given the 10 years of experience yielded from participants and the CMS Innovation Center model tests. The BPCI Advanced and CJR models are still being tested, and the effects of the models' care redesign changes aimed to achieve Medicare savings and maintain or improve quality of care are still being evaluated, see section X.A.2.c. of the preamble of this proposed rule, but have generated evidence from multiple evaluation reports to support the design of TEAM. Beyond quantitative data, qualitative data collected from model participants and data from site visits indicate care transformation is happening, and quality of care is improving across the spectrum. Qualitative data range from reported improved relationships between inpatient providers and post-acute care (PAC) providers, to reshaping patient and provider expectations about appropriate discharge destinations, to process changes, such as standardized care pathways, identification and mitigation of medical and social risk factors, monitoring patients in the post-discharge period, and connecting patients to primary care providers. As noted in section X.A.2.c. of the preamble of this proposed rule, evaluation results from the previous and current episode-based payment models consistently indicate that these models can reduce episode payments, before

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[566] Tsai, T. C., Greaves, F., Zheng, J., Orav, E. J., Zinner, M. J., & Jha, A. K. (2016). Better patient care at High-Quality hospitals may save Medicare money and bolster Episode-Based payment models. Health Affairs, 35(9), 1681–1689. *https://doi.org/10.1377/hlthaff.2016.0361.*

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considering incentive payments, and generally without compromising quality of care.

c. ACE, BPCI, BPCI Advanced, and CJR Evaluation Results

The CMS Innovation Center previously tested episode-based payment approaches among acute episodes, including the Medicare Acute Care Episode (ACE) demonstration and the BPCI Initiative, and currently is testing additional approaches under the BPCI Advanced model and the CJR model.[573] The ACE demonstration tested a bundled payment approach for cardiac and orthopedic inpatient surgical services and procedures. All Medicare Part A and Part B services pertaining to the inpatient stay were included in the ACE demonstration episodes of care. Evaluations results found that Medicare saved an average of $585 per episode from the combined Medicare Part A and B expected payments or a total of $7.3 million across all episodes (12,501 episodes), all ACE MS–DRGs, and four ACE Sites. However, increases in post-acute care spending reduced these savings by approximately 45 percent, resulting in per episode savings of $319 and total net savings of approximately $4 million. With respect to quality of care, findings suggest that the ACE sites maintained their quality-of-care levels without any systematic or consistent changes in clinical outcomes or in the type of patients they admitted in response to the demonstration. Despite the lack of strong quantitative evidence for realized improvements in quality, there was qualitative evidence that hospitals worked to improve processes and outcomes.[574]

The BPCI initiative tested whether linking payments for providers that furnish Medicare-covered items and services during an episode related to an inpatient hospitalization could reduce Medicare expenditures while maintaining or improving quality of care.

- Model 1 episodes were limited to the acute inpatient hospitalizations for all MS–DRGs.
- Model 2 episodes began with a hospital admission and extended for 30, 60, or 90 days after discharge.
- Model 3 episodes began with the initiation of post-acute care following a hospital admission and extended for 30, 60, or 90 days.
- Model 4 episodes began with a hospital admission and included readmissions within 30 days after discharge.

Model 1 was unique, as compared to Models 2–4, in that target prices weren't generated but awardees received a predetermined discount percentage to their Medicare Inpatient payment system (IPPS) operating payment rates for episodes at their hospital. Model 1 had a small volume of participants, however, evaluation results found that there were no consistent negative or positive statistically significant impacts to Medicare payments or quality of care effects on Medicare beneficiaries.[575] Similarly, Model 4 had a small volume of participants, and by the end of the model there was no change in allowed payments nor were there any changes in the quality of care as measured by claims-based quality measures.[576]

Evaluation results for BPCI Models 2 and 3 were more robust given the greater volume of participants in each model. Similar to Model 1 and Model 4, quality of care generally remained unchanged in BPCI Models 2 and 3. With respect to the financial performance of the models, findings demonstrated reductions in FFS payments of $1,193 million for Model 2 and $232 million for Model 3. However, Medicare experienced net losses of $418 million ($p<0.05$) for Model 2, or $332 per episode, and $110 million ($p<0.05$) for Model 3, or $714 per episode, after accounting for reconciliation payments to participants. These net losses to Medicare represented 1.3% of what payments would have been absent BPCI under Model 2 and 3.1% under Model 3. The largest contributing factor to these losses was the elimination of participants' repayment responsibility. If CMS had not eliminated repayment responsibility, and assuming model participation remained the same, Model 2 would have resulted in no net losses or savings, and net losses under Model 3 would have been reduced to $ 66 million ($p<0.05$), or 1.9% of what payments would have been absent BPCI.[577]

We currently are testing the BPCI Advanced model, which is a voluntary episode-based model based on the BPCI Initiative's Model 2, that tests whether linking payments for an episode will incentivize health care providers to invest in innovation and care redesign to improve care coordination and reduce expenditures, while maintaining or improving the quality of care for Medicare FFS beneficiaries. We are still evaluating the effects of the BPCI Advanced model on patient experience of care, quality outcomes, and cost of care for Medicare FFS beneficiaries. However, evaluation results to date demonstrated reductions in episode payments and maintenance of quality of care, but the model has thus far been unable to generate Medicare savings. As of Model Year 3 (2020), BPCI Advanced participants reduced average episode payments by 3.8% or $1,028 per episode, and more specifically 3.1% ($796 per episode) for medical episodes and 5.8% ($1,800 per episode) for surgical episodes. Despite the reductions in FFS payments, after accounting for reconciliation payments to participants, Medicare had a net loss of $114 million in 2020, or 0.8% of what Medicare payments would have been in absence of the model. When looking at Medicare savings by episode type, surgical episodes resulted in an estimated net savings of $71.3 million, or 2.3%, but those savings were offset by medical episodes which resulted in an estimated net loss of $200.5 million, or 1.9%.[578] The BPCI Advanced model implemented changes, most notably in 2021–23, and most recently made further changes to extend the model through 2025 and support provider engagement in value-based care.

We are also currently testing the CJR model, which is a mandatory episode-based payment model in 34 metropolitan statistical areas (MSAs) for lower extremity joint replacement episodes that encourages hospitals, physicians, and PAC providers to work

[573] Medicare Acute Care Episode Demonstration (*https://innovation.cms.gov/innovation-models/ace*), BPCI Initiative (*https://www.cms.gov/priorities/innovation/innovation-models/bundled-payments*), BPCI Advanced Model (*https://www.cms.gov/priorities/innovation/innovation-models/bpci-advanced*), CJR Model (*https://www.cms.gov/priorities/innovation/innovation-models/CJR*).

[574] Evaluation of the Medicare Acute Care Episode (ACE) Demonstration. (2013). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.*

[575] Evaluation and Monitoring of the Bundled Payments for Care Improvement Model 1 Initiative. (2016). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/files/reports/bpci-mdl1yr2annrpt.pdf.*

[576] CMS Bundled Payments for Care Improvement Initiative Models 2–4: Year 7 Evaluation & Monitoring Annual Report. (2021). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2021/bpci-models2-4-yr7evalrpt.*

[577] CMS Bundled Payments for Care Improvement Initiative Models 2–4: Year 7 Evaluation & Monitoring Annual Report. (2021). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2021/bpci-models2-4-yr7evalrpt.*

[578] CMS Bundled Payments for Care Improvement Advanced Model: Fourth Evaluation Report. (2023). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2023/bpci-adv-ar4.*

together to improve the quality and coordination of care from the initial hospitalization or outpatient procedure through recovery. Evaluation results to date have indicated that in the first four performance years, mandatory hospitals generated $72 million dollars in savings to Medicare, although not statistically significant. But in Performance Year 5, reconciliation payments substantially increased generating $95.4M in statistically significant Medicare losses, due to adjustments made to the model made during the COVID–19 Public Health Emergency (PHE). CMS enacted these temporary adjustments, which effectively waived downside risk for all CJR episodes, in order to minimize any financial burden associated with model participation given the financial challenges and uncertainties hospitals faced early in the COVID–19 PHE. These adjustments resulted in reconciliation payments being triple what they were in previous years, which reversed the savings trajectory and resulted in statistically significant losses to Medicare for mandatory hospitals. The losses in Performance Year 5 were large enough to offset total estimated savings prior to the public health emergency.[579] Like the BPCI Advanced model, the CJR model was revised and extended until December 31, 2024.

We believe that providers', suppliers', and CMS' experiences with the BPCI Advanced and CJR models support the design of the proposed TEAM. Stakeholders both directly and indirectly involved in testing the BPCI Advanced and CJR models have conveyed that they perceive episode-based payments to be an effective mechanism for advancing better, more accountable care through care coordination and opportunities to improve care efficiency. CMS has also heard similar sentiment through other efforts including the CMS Innovation Center's Specialty Care Strategy Listening Session and recent Episode-based Payment Model Request for Information (RFI) (88 FR 45872).[580]

Further information of why specific elements of the models and initiatives were incorporated into the TEAM's designs is discussed later in this proposed rule.

d. CMS Innovation Center Specialty Care Strategy

In 2021, the CMS Innovation Center announced a strategic refresh with a vision of having a health care system that achieves equitable outcomes through high quality, affordable, person-centered care.[581] To guide this updated vision, the CMS Innovation Center intends to design, implement, and evaluate future models with a focus on five strategic objectives: (i) driving accountable care; (ii) advancing health equity; (iii) supporting innovation; (iv) addressing affordability; and (v) partnering to achieve system transformation. One of the goals established by the strategic refresh was having 100% of traditional Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030. This means that beneficiaries should experience longitudinal, accountable care with providers that are responsible for the quality and total cost of their care. Beneficiaries will experience accountable care relationships mostly through advanced primary care or accountable care organizations (ACOs), and these entities are expected to coordinate with or fully integrate specialty care to deliver whole-person care.

To support specialty care integration, the CMS Innovation Center released a comprehensive specialty strategy to test models and innovations supporting access to high-quality, integrated specialty care across the patient journey—both longitudinally and for procedural or acute services.[582] Specialty integration cannot be achieved with a single approach given a beneficiary's health needs may change influencing the types of providers and settings where they receive care. Therefore, the specialty care strategy consists of four elements: (i) enhancing specialty care performance data transparency; (ii) maintaining momentum on acute episode payment models and condition-based models; (iii) creating financial incentives within primary care for specialist engagement; and (iv) creating financial incentives for specialists to affiliate with population-based models and move to value-based care. The proposed TEAM falls within the second element of the specialty care strategy and utilizes lessons learned from our experience with the BPCI Advanced model and the CJR model to design TEAM as a new episode-based payment model that would focus on accountability for quality and cost, health equity, and specialty integration. TEAM is further informed by the Episode-Based Payment Model RFI (88 FR 45872) published in July 2023, which gathered public comment on potential model design elements.

The proposed TEAM represents one aspect of the specialty care strategy, and does not capture all beneficiaries, providers, and care settings to achieve complete person-centered value-based care on its own. Improving the health care system for Medicare beneficiaries requires a comprehensive approach that cannot be addressed by a single model or initiative since beneficiary health care needs are dynamic across the patient care continuum. This means TEAM would center accountability on beneficiary health care needs during narrow, focused periods of acute and post-acute care while health care needs outside of this scope would be addressed with other elements of the specialty care strategy. Therefore, we believe TEAM would complement other elements of the specialty care strategy (for example, another element of the strategy is to share TEAM-style episode data with ACOs) and would promote care transformation that generates standard care pathways and new best practices across broad patient populations (not just Medicare FFS).

3. Provisions of Proposed Transforming Episode Accountability Model

a. Model Performance Period, TEAM Participants, Participation Tracks, and Geographic Area Selection

(1) Model Performance Period

We are proposing a 5-year ''model performance period'', defined as the 60-month period from January 1, 2026, to December 31, 2030, during which TEAM is being tested and the TEAM participants is held accountable for spending and quality. The model would have 5 ''performance years'' (PYs), which we propose to define as a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period in which TEAM is being tested and TEAM participants are held accountable for spending and quality. We are proposing to define the start of the model performance period as the ''model start date''.

We are proposing a 5-year model performance period to allow for a sufficient time period for TEAM

[579] CMS Comprehensive Care for Joint Replacement Model: Performance Year 5 Evaluation Report. (2023). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report.*

[580] CMS Innovation Center's Specialty Care Strategy Listening Session (*https://www.cms.gov/priorities/innovation/media/document/spec-care-listening-session-slides*).

[581] Centers for Medicare & Medicaid Services. (2021). Innovation Center Strategy Refresh. *https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.*

[582] The CMS Innovation Center's strategy to support person-centered, value-based specialty care | CMS. (2022). *https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care#_ftn1.*

Participants to invest in care delivery transformation and observe return on investments. A five-year period would also allow for an adequate evaluation period to determine model results, given that many of the episode categories we are proposing to test under TEAM have thus far only been tested among voluntary model participants.

We alternatively considered a 3- or 10-year model performance period. However, we believe a 3-year period to be too short to allow adequate time to invest in transformations and achieve considerable model savings to the Medicare trust fund. We also considered a 10-year model performance period, similar to several recently announced CMS Innovation Center models; however, given this would be a mandatory model, we believe 5 years would be sufficient to gather the necessary data to evaluate whether the model is successful for the included episode categories.

We also considered beginning TEAM on April 1, 2026, July 1, 2026, or October 1, 2026, to allow selected TEAM participants more time to prepare for model implementation. However, based on our experience with prior and current episode-based payment models, we believe that potential participants would have sufficient time to prepare to participate in a model that begins January 1, 2026, which is why we are proposing TEAM at least 18 months before the proposed model start date. In addition, given that the current BPCI Advanced model concludes on December 31, 2025, beginning TEAM on January 1, 2026, would ensure continuity between models for those hospitals in BPCI Advanced that are in the CBSAs selected to participate in TEAM. We also recognize the potential misalignment between the performance measurement period based on the calendar year and an alternative model start date, so if we were to adjust the model start date based on public input, we propose that we would also alter the model performance period. For example, if TEAM were to begin April 1, 2026, the PY would still be defined as a 12-month period from the start date, meaning April 1, 2026, to March 31, 2027. As a result, the model performance period end date would also shift to reflect a 60-month period from the model start date of the first PY—for example, April 1, 2026, to March 31, 2031.

We seek comment on the proposed model performance period of 5 years and proposed model start date of January 1, 2026, for Performance Year 1, and on the alternatively considered start dates (April 1, 2026, July 1, 2026, and October 1, 2026), and the subsequent adjustment to dates of the model performance period if we were to change the model start date.

(2) Participants

(a) Background

The proposed TEAM builds upon previous CMS Innovation Center episode-based payment models, including the BPCI Advanced and CJR models. While these models have similarities, they have some notable differences with regard to participant structure and the entity who can initiate episodes. The BPCI Advanced model is a voluntary model that includes convener and non-convener participants. A non-convener participant initiates episodes, is either an acute care hospital or physician group practice (PGP) and bears financial risk for itself. A convener participant is an entity willing to bear financial risk for downstream episode initiators, either acute care hospitals or PGPs, and generally provides supportive services such as data analytics or clinical care navigators. In contrast, the CJR model is a mandatory model in 34 MSAs that does not include convener participants or allow PGPs to initiate episodes but does parallel BPCI Advanced by including participant hospitals (non-convener) that initiate episodes. While the CJR Model does not have a formal convener role, some CJR participant hospitals contract with (non-model participant) convener-organizations to provide administrative, operational, analytical, and clinical services.

We are interested in testing and evaluating the impact of a mandatory episode-based payment model in selected geographic areas, see section X.A.3.a.(4) of the preamble of this proposed rule, for acute care hospitals that initiate certain episode categories, including among those hospitals that have not chosen to voluntarily participate in the BPCI Advanced model or those that were selected to participate in the CJR model. Testing the model among acute care hospitals in select geographic areas would allow CMS and participants to gain experience testing and evaluating an episode-based payment approach for certain episodes furnished by hospitals with a variety of historic utilization patterns; roles within their local markets, including with regard to accountable care organization participation or affiliation; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Further, Medicare beneficiaries and providers in rural and underserved areas can be underrepresented in voluntary models, whereas under a mandatory model we may include these entities, with safeguards as appropriate, for participation so that beneficiaries have equitable access to care redesign approaches intended to improve the quality care, and such providers gain experience in value-based care. Lastly, participation of hospitals in selected geographic areas would allow CMS to test episode-based payments without introducing participant attrition or selection bias such as the selection bias inherent in the BPCI Advanced model due to self-selected participation in the model and self-selection of episode categories.

(b) Proposed TEAM Participant Definition

As previously discussed, the CJR model has participant hospitals who are acute care hospitals that initiate episodes whereas the BPCI Advanced model allows either acute care hospitals or PGPs to initiate episodes, who may or may not be the participant in the model. Since two different types of entities are permitted to initiate episodes and they may be co-located, meaning the PGP may initiate episodes and practices at a hospital that also initiates episodes, the BPCI Advanced model includes precedence rules. Precedence rules dictate which entity will be attributed the episode and accountable for quality and cost performance, but they also contribute to operational complexity. For example, in BPCI Advanced a single episode could be attributed to one of three potential provider or suppliers: the attending PGP, the operating PGP, or the hospital. Data feeds can help inform entities of episode attribution when multiple provider or suppliers have interacted with the beneficiary, but BPCI Advanced participants have expressed challenges with identifying their potential episodes due to lack of real-time data.

Given the challenges of having multiple provider or suppliers in a single model initiate an episode, we believe it would benefit TEAM to only allow a single entity to initiate episodes and be the participant in TEAM. This is because it would simplify episode attribution, meaning it would avoid precedence rules, and make it easier for the single entity to identify beneficiaries that may be included in the model. Therefore, similar to the CJR model, we propose that acute care hospitals would be the TEAM participant and the only entity able to initiate an episode in TEAM. Specifically, we propose defining a TEAM participant as an acute

care hospital that initiates episodes and paid under the IPPS with a CMS Certification Number (CCN) primary address located in one of the geographic areas selected for participation in TEAM, as described in section X.A.3.a.(4) of the preamble of this proposed rule. We are also proposing that the term ''hospital'' has the same meaning as hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS.

We believe that hospitals are more likely than other providers or suppliers to have an adequate volume of episodes to justify an investment in episode management. We also believe that hospitals, compared to other providers or suppliers, are most likely to have access to resources that would allow them to appropriately manage and coordinate care throughout these episodes. Further, the hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient PAC service delivery provides substantial opportunities for improving quality and reducing costs in TEAM.

We also believe hospitals being TEAM participants aligns with how episodes are initiated in TEAM, as described in section X.A.3.b.(5)(c) of the preamble of this proposed rule, since it relies on a beneficiary's inpatient admission to a hospital or a beneficiary receiving a procedure in a hospital outpatient department. Additionally, we believe that utilizing the hospital as the TEAM participant is a straightforward approach for this model because the hospital furnishes the acute surgical procedure and plans for and manages post-discharge (or post-procedure) care. We also want to test a broad model in a variety of hospitals, including safety net hospitals specified in section X.A.3.f.(2) and rural hospitals specified in section X.A.3.f.(3) of the preamble of this proposed rule, under TEAM to examine results from a more generalized payment model. Finally, as described in the following sections that present our proposed approach to geographic area selection, our geographic area selection approach relies upon our definition of hospitals as the TEAM participant and the entity that initiates episodes.

We seek comment on our proposal at § 512.505 to define TEAM participants as an acute care hospital that initiates episodes and paid under the IPPS with a CMS CCN primary address located in one of the geographic areas selected for participation in TEAM. We also seek comment on our proposal at § 512.505 to define hospital as defined in section 1886(d)(1)(B) of the Act.

(i) TEAM Participant Exclusions and Considerations

Under this proposal, all acute care hospitals in Maryland would be excluded from being TEAM participants because Maryland hospitals are not currently paid under the IPPS and OPPS. Therefore, any acute care hospital located in Maryland would not be able to satisfy the definition of TEAM participant. Currently, CMS and the State of Maryland are testing the Maryland Total Cost of Care (TCOC) Model, which sets a per capita limit on Medicare total cost of care in Maryland. The TCOC Model holds the State fully at risk for the total cost of care for Medicare beneficiaries. Maryland acute care hospitals are not paid under the IPPS or OPPS, but rather are paid using a global budget methodology that establishes pricing of medical services provided by hospitals, primary care doctors, and specialists across all payers. Therefore, we are also proposing that payments to Maryland acute care hospitals would be excluded in the pricing calculations as described in section X.A.3.d. of the preamble of this proposed rule. We seek comment on this proposal and whether there are potential approaches for including Maryland acute care hospitals as TEAM participants. In addition, we seek comment on whether Maryland hospitals should be TEAM participants in the future.

We also recognize that the Maryland TCOC Model may not be the only CMS model or initiative that may use hospital global budgets as part of their alternative payment models. The States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model is a State-based voluntary TCOC model that will incorporate hospital global budgets. There are several cohorts in which states may participate, and we expect that the AHEAD Model implementation period would overlap with the performance years of TEAM. Given that CMS envisions that up to eight states would participate in the AHEAD Model, unlike the Maryland TCOC Model, we are hesitant to propose excluding hospitals that participate in the AHEAD Model from being TEAM participants because it may reduce the volume of beneficiaries that may benefit from episodic, acute coordinated care. We are also aware that allowing overlap may introduce model complexities with respect to constructing TEAM prices or the AHEAD global budgets and statewide total cost of care calculations. However, there may be other opportunities, such as sharing of TEAM-style summary episode data (not beneficiary-identifiable) with AHEAD hospitals, to support episodes without allowing hospitals participating in the AHEAD Model to participate in TEAM as TEAM participants. Thus, we are unsure if we should allow AHEAD hospitals located in areas selected for TEAM participation to participate in TEAM as TEAM participants. We seek comment on whether there may be potential approaches for including hospitals participating in the AHEAD Model in TEAM as TEAM participants, or other approaches that may not result in participation in both models but support the integration of episodes and hospital global budgets. We gather that the AHEAD Model would be voluntary for participating states and hospitals within those states, and as such, we also seek comment on whether hospitals located in AHEAD states should be required to participate in TEAM as TEAM participants if they either do not participate in in the AHEAD Model or if they terminate their participation in the AHEAD Model (or CMS terminates them) before the AHEAD Model ends.

Since TEAM is built from lessons learned from previous episode-based payment models, including the BPCI Advanced model, we considered including PGPs in the definition of TEAM participant in the future. We recognize that PGPs demonstrated some successes in the BPCI Advanced model, most specifically that BPCI Advanced PGPs reduced average episode payments by $2,157 for surgical episodes in Model Year 3 (2020) and reduced unplanned hospital readmissions for surgical episodes in Model Years 1&2 (October 2018–December 2019).[583] [584] Despite these favorable findings, we have concerns about requiring PGPs, who are generally smaller entities and care for a lower volume of Medicare beneficiaries, to participate in an Advanced APM such as TEAM given the more than nominal financial risk standard required of Advanced APMs set forth in 42 CFR 414.1415I. While BPCI Advanced is an Advanced APM, participation is voluntary, and PGPs have the autonomy to determine if they have the infrastructure and resources to take on

[583] CMS Bundled Payments for Care Improvement Advanced Model: Third Evaluation Report. (2022). Centers for Medicare & Medicaid Services. Retrieved November 28, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2022/bpci-adv-ar3.*

[584] CMS Bundled Payments for Care Improvement Advanced Model: Year 2 Evaluation Report. (2021). Centers for Medicare & Medicaid Services. Retrieved November 28, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2021/bpci-yr2-annual-report.*

the level of financial risk to participate in the model and determine if they have sufficient episode volume to create systematic care redesign efficiencies. Further, most eligible clinicians in the BPCI Advanced model do not meet Qualifying APM Participant determinations in the model due to not meeting the required thresholds for Medicare Part B payments or Medicare beneficiaries, suggesting that acute care-based episodes may not sufficiently capture the full panel of patients a PGP manages. We believe there are other meaningful opportunities for PGPs to engage in TEAM, specifically through financial arrangements with TEAM participants, or through other CMS value-based care initiatives, including future PGP-specific opportunities under development through the CMS Innovation Center specialty care strategy. For these reasons, we are not proposing PGPs to be included in the definition of TEAM participant in TEAM at this time. However, we seek comment on whether we should include PGPs in the definition of TEAM participant through future rulemaking, or if there are other ways, beyond financial arrangements, that we can incorporate PGPs to promote collaboration between TEAM participants and other providers who may care for a TEAM beneficiary over the course of the episode.

We seek comment on our proposal to exclude hospitals located in Maryland from TEAM participation, and how to address hospitals that would participate in the AHEAD model. We also seek comment on including PGPs in the definition of TEAM participant.

(c) Proposed Mandatory Participation

We are proposing to require hospitals located in selected geographic areas, as described in section X.A.3.a.(4) of the preamble of this proposed rule, that meet the proposed TEAM participant definition to participate in TEAM. Such hospitals would be required to participate in the Model even if they have not had previous episode-based payment model or value-based care experience. Shifting hospitals away from the traditional Medicare FFS payment system to value-based care may require significant time, effort, and resources to build infrastructure and establish care redesign processes.[585] We intend to provide sufficient time for potential TEAM participants to prepare for model implementation, which is why we are proposing TEAM at least 18 months before the proposed model start date. However, we acknowledge that time alone may not be adequate to prepare TEAM participants for model participation, especially those with limited or no value-based care experience. We seek comment on whether 1 year would be a sufficient amount of time for hospitals required to participate in TEAM to prepare for TEAM participation or whether a longer timeframe (for example, 18 months) or shorter timeframe (for example, 6 months) would be sufficient time for hospitals to prepare to become TEAM participants, effective on the model start date.

We alternatively considered making participation in TEAM voluntary. However, we would be concerned that a fully voluntary model would not lead to meaningful evaluation findings especially since the CMS Innovation Center has tested voluntary episode-based payment models for over a decade. We recognize that a mandatory model test limits the selection of participants to only those captured within the selected geographic areas. We also recognize there may be participants of previous or current models that wish to continue their care redesign efforts, further care transformation, and maintain efficiencies to avoid reliance on the volume-based FFS payment system. We considered allowing hospitals that have previously participated (or are currently participating) in a Medicare episode-based payment model to voluntarily opt-into TEAM to increase the footprint of the model and allow those entities to maintain their momentum in value-based care. However, we recognize several challenges with including a voluntary opt-in for a model such as TEAM. First, allowing an opt-in may limit the ability of the model to achieve Medicare savings, given that opt-in participants may self-select into the model based on their belief that they would benefit financially. Second, an opt-in may compromise the rigor of our evaluation of TEAM, because it could limit the number of hospitals available for our comparison group and our ability to detect generalizable evaluation results, due to participant self-selection into the model. Finally, we note that we have been testing the five episode categories that we have proposed to include in TEAM, as described in section X.A.3.b. of the preamble of this proposed rule, on a voluntary basis via BPCI Advanced and the BPCI Initiative, so we have a significant amount of data on the performance of those episode categories in a voluntary structure already.

For these reasons, we are not proposing a voluntary opt-in participation arm to TEAM. However, for the reasons discussed below, we are considering and seek comment regarding a voluntary opt-in participation arm in the proposed TEAM. Specifically, we are considering limiting voluntary opt-in participation to TEAM for hospitals that currently participate in the BPCI Advanced or the CJR model, that are not located in an area mandated for TEAM participation, and continue to participate until completion, of the model in which they are currently participating.[586] For those hospitals that meet this criteria and that would want to voluntarily opt into TEAM participation, we would require those hospitals to participate in all TEAM episode categories for the full five-year model performance period and they would not be permitted to voluntarily terminate model participation. The TEAM voluntary opt-in would be a one-time opportunity to join TEAM participation and those hospitals would need to complete and submit an application to CMS in a form and manner and by a date specified by CMS, prior to the first performance year of TEAM. Further, hospitals that submit an application would need to undergo and pass at minimum multiple levels of program integrity and law enforcement screening. Hospitals that pass screening would be offered a participation agreement from CMS to participate in TEAM, which would at minimum subject them to all the same terms, conditions and requirements of those hospitals mandated to participate in TEAM. Lastly, hospitals offered a participation agreement to voluntarily opt into TEAM would be required to submit and execute a participation agreement with CMS in a manner and form, and by a date specified by CMS prior to the model start date.

We believe that offering this potential voluntary opt-in consideration would allow those hospitals that have made significant investments in care redesign and episode management to further their efforts to improve beneficiary quality of care and reduce Medicare spending. We recognize the pool of hospitals that could potentially apply for voluntary opt-in participation may be narrow. However, we believe extending the voluntary opt-in opportunity to hospitals that terminated

[585] Erikson, C., Pittman, P., LaFrance, A., & Chapman, S. (2017). Alternative payment models lead to strategic care coordination workforce investments. Nursing Outlook, 65(6), 737–745. *https://doi.org/10.1016/j.outlook.2017.04.001.*

[586] Current BPCI Advanced hospitals would need to participate in BPCI Advanced until December 31, 2025 and current CJR participant hospitals would need to participate in the CJR model until December 31, 2024.

BPCI Advanced or CJR model participation or to hospitals not mandated to participate in TEAM would jeopardize the model's ability to have a robust evaluation. This is because we would want to ensure we have a sufficient comparison group of hospitals not participating in TEAM to produce generalizable findings. As previously indicated, we are not proposing a voluntary opt-in participation arm to TEAM; however, we are considering and seek comment regarding a voluntary opt-in participation arm in the proposed TEAM. Lastly, we seek comment on our proposal for hospitals located in selected geographic areas that meet the proposed TEAM participant definition to participate in TEAM.

(d) Financial Accountability of a TEAM Participant

As we did with the CJR model, we continue to believe it is most appropriate to identify a single entity to bear financial accountability for making repayment if quality and spending performance metrics are not met to CMS under the model after reconciliation has been performed. Consistent with the CJR model, we propose to make TEAM participants financially accountable for the episode for the following reasons:

- We believe hospitals would play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing services related to episodes. A large portion of a beneficiary's recovery trajectory from an episode would begin during the hospital inpatient stay or procedure performed in the hospital outpatient department.
- Most hospitals already have some infrastructure related to health information technology, patient and family education, and care management and discharge planning. This infrastructure includes post-acute care coordination infrastructure and resources such as case managers, which hospitals can build upon to achieve efficiencies under TEAM.
- We are proposing that episodes in TEAM begin with an acute care hospital stay or hospital outpatient department procedure visit. Some episodes may be preceded by an emergency room visit and possible transfer from another hospital's emergency room, or followed by PAC. However, we do not believe it would be appropriate to hold a PAC provider or a hospital other than the TEAM participant where the inpatient stay or initial hospital outpatient procedure that initiated the episode happened fully financially accountable for an episode under this model.

Episodes in TEAM may be associated with multiple hospitalizations through readmissions or transfers. When more than one hospitalization occurs during a single episode, we propose to hold the TEAM participant to which the episode is initiated, as described in section X.A.3.b.(5)(c) of the preamble of this proposed rule, financially accountable for the episode nonetheless. We recognize that, particularly where the hospital admission may be preceded by an emergency room visit and subsequent transfer to a tertiary or other regional hospital facility, patients often wish to return home to their local area for post-acute care. Many hospitals have recently heightened their focus on aligning their efforts with those of community providers, both those in the immediate area as well as more outlying areas from which they receive transfers and referrals, to provide an improved continuum of care. In many cases, this heightened focus on alignment is due to the incentives under other CMS models and programs, including ACO initiatives such as the Shared Savings Program or the Hospital Readmissions Reduction Program (HRRP). By focusing on the TEAM participant as the accountable or financially responsible entity, we hope to continue to encourage this coordination across providers and seek comment on ways we can best encourage these relationships within the scope of TEAM.

We seek comment on our proposal to require TEAM participants to be financially accountable for episodes in TEAM.

(i) Financial Accountability Considerations

We recognize in the proposed TEAM that a beneficiary in an episode may receive care from multiple providers and suppliers, and not just from the TEAM participant where the episode was initiated. We considered allowing providers or suppliers, other than the TEAM participant, to bear financial accountability for episodes given their involvement in a TEAM beneficiary's care. Specifically, we considered splitting financial accountability between the TEAM participant and other providers and suppliers that provide items and services to the TEAM beneficiary. For example, we considered the TEAM participant being financially accountable for a majority of the episode spending, such as all Medicare Part A spending, and other suppliers, such as PGPs, being accountable for a portion episode spending related to Medicare Part B spending. However, we have concerns about how to accurately determine a reasonable sharing methodology that reflects the portion of spending either the TEAM participant or the PGP should be financially accountable for. Further, we have concerns about requiring PGPs to be financially accountable given practices can vary by size and resources. As previously noted, the BPCI Advanced model includes PGPs, and the physician groups electing to participate in BPCI Advanced have done so because their practice structure supports care redesign and other infrastructure necessary to bear financial accountability for episodes. However, these physician groups are not necessarily representative of the typical group practice. The infrastructure necessary to accept financial accountability for episodes is not present across all PGPs, and thus we do not believe it would be appropriate to designate PGPs to bear a portion of the financial accountability for episodes under the proposed TEAM. Further, shared financial accountability would require more than hospitals being TEAM participants and introduces model complexity. We seek comment on approaches to splitting financial accountability when multiple providers care for a single beneficiary in an episode.

While we propose that the TEAM participant be financially responsible for the episode, we also believe that effective care redesign requires meaningful collaboration among acute care hospitals, PAC providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers and suppliers to be aligned and engaged, financially and otherwise, with the TEAM participants, with the potential to share financial accountability for an episode with those TEAM participants. We note that all relationships between and among TEAM participants and other providers and suppliers would still need to comply with all relevant laws and regulations, including the fraud and abuse laws and all Medicare payment and coverage requirements unless otherwise specified further in this section and in section X.A.3.g of the preamble of this proposed rule. Depending on a TEAM participant's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers may be important, although not necessarily required, for TEAM success in a community. We acknowledge that there may need to be incentives for other providers and suppliers to partner with TEAM

participants and develop strategies to improve episode efficiency.

We acknowledge the important role that conveners play in the BPCI Advanced model with regard to providing financial responsibility and infrastructure support to hospitals and PGPs participation in BPCI Advanced. The convener relationship (where another entity assumes financial responsibility) may take numerous forms, including contractual (such as a separate for-profit company that agrees to take on a hospital or PGP's financial risk in the hopes of achieving financial gain through better management of the episodes) and through ownership (such as when risk is borne at a corporate level within a hospital chain). We considered allowing convener entities, like those recognized in the BPCI Advanced model, to have formal roles in TEAM. At peak BPCI Advanced participation, over 70%, or 1,439, of the hospitals and PGPs in Model Year 3 (2020) participated as downstream episode initiators under one of the 92 convener participants.[587] While the majority of BPCI Advanced hospitals and PGPs participated under a convener participant, some hospitals and PGPs found the participation relationship with a convener challenging. Specifically, some hospitals and PGPs felt removed from participation decisions since they were not party to the participation agreement between CMS and the convener participant. Additionally, convener participants that are not Medicare providers or suppliers may need financial guarantees that can impose significant upfront financial investment for participation and be administratively burdensome for CMS and the participant. We are not proposing to require convener entities in this model and we do not intend to identify or require any Medicare-enrolled providers or suppliers (or providers and suppliers that are not enrolled in Medicare) to be convener entities in TEAM, in light of the experiences and resources that would be needed to ''convene'' over one or more TEAM participants. As with the CJR model, we do not intend to restrict the ability of TEAM participants to enter into administrative or risk sharing arrangements related to TEAM with entities that may provide similar support as a convener, except to the extent that such arrangements are already restricted or prohibited by existing law. We are also not proposing to require TEAM participants to partner with convener entities and we are not proposing to require any entities, providers, or suppliers to serve as conveners for purposes of TEAM. We refer readers to section X.A.3.g. of the preamble of this proposed rule for further discussion of model design elements that may outline financial arrangements between TEAM participants and other providers and suppliers.

We seek comment on approaches to splitting financial accountability when multiple providers or suppliers care for a single beneficiary in an episode.

(3) TEAM Participation Tracks

One way to help providers and suppliers gain experience in alternative payment models is through model participation tracks where the levels of risk and reward are reduced while the participants establish and hone their care redesign processes. Stakeholders have urged CMS to offer a glide path in its models, most recently in the Episode-based Payment Model RFI (88 FR 45872), to smooth the transition to risk. Such a glide path could provide more time for participants to gain experience with two-sided financial risk by phasing-in risk rather than requiring full-risk participation at the start of the model. Previous and current CMS models and programs have implemented this approach, including the recently announced Making Care Primary Model, which offers a progressive three-track approach that increases participants' accountability, and the Medicare Shared Savings Program, which offers an incremental glide path for ACOs to transition to higher levels of potential risk and reward. We note that these models and programs have longer durations than the model duration that we are proposing in TEAM, which makes it easier to offer a gradual transition to two-sided financial risk or higher levels of risk and reward. However, in light of our proposal to make TEAM a five-year model test, we believe that TEAM participants would still benefit from the opportunity to ease into two-sided financial risk participation as they develop efficiencies.

We are proposing that there will be three tracks in TEAM, each with differing financial risk and quality performance adjustments. Track 1 would be available only in PY 1 for all TEAM participants and would have only upside financial risk with quality adjustment applied to positive reconciliation amounts. Track 2 would be available in PYs 2 through 5 to a limited set of TEAM participants, including safety net hospitals, and would have two-sided financial risk with quality adjustment to reconciliation amounts. Lastly, Track 3 would be available in PYs 1 through 5 for all TEAM Participants and would have two-sided financial risk with quality adjustment to reconciliation amounts.

We are proposing a one-year glide path to two-sided risk for TEAM participants in an effort to ensure that TEAM participants have time to prepare for two-sided financial risk. We are proposing to allow all TEAM participants to select between one of two tracks for the first performance year of TEAM. For PY 1, a TEAM participant may elect to participate in either Track 1 or Track 3. For PY 1, Track 1 would have upside-only financial risk provided through reconciliation payments, subject to a 10% stop-gain limit and a Composite Quality Score (CQS) adjustment percentage of up to 10%, as described in sections X.A.3.d.(5)(h) and X.A.3.d.(5)(g) of the preamble of this proposed rule, that would allow TEAM participants to be rewarded for their work to improve quality and cost outcomes for their episodes, but not be held financially accountable if spending exceeds the reconciliation target price. We believe the 10% stop-gain limit and a CQS adjustment percentage of up to 10% for Track 1 are appropriate and would allow TEAM participants to be rewarded for spending and quality performance while easing into financial risk. We propose that Track 3 would have two-sided financial risk in the form of reconciliation payments or repayment amounts, subject to 20% stop-gain and stop-loss limits and a CQS adjustment percentage of up to 10%, as described in sections X.A.3.d.(5)(h) and X.A.3.d.(5)(g) of the preamble of this proposed rule, that would allow TEAM participants to have higher levels of reward and risk based on their quality and cost performance for their episodes. We are proposing to only allow TEAM participants to participate in Track 1 for one performance year, specifically PY 1. We are proposing a five-year model test, and we do not believe that making Track 1 available for more than one performance year would motivate TEAM participants to improve quality or spending performance since there would be no financial accountability when spending reductions are not achieved.

We believe a one-year glide path is an appropriate length of time for a five-year model test that aims to improve patient quality of care and reduce Medicare

[587] CMS Bundled Payments for Care Improvement Advanced Model: Year 2 Evaluation Report. (2021). Centers for Medicare & Medicaid Services. Retrieved November 28, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2021/bpci-yr2-annual-report.*

spending. We considered limiting eligibility for Track 1 during PY 1 to TEAM participants that have not previously participated in a Medicare episode-based payment model, but given that TEAM would be a mandatory model, we believe prior experience does not guarantee successful participation, and that it is important for TEAM participants to consider their own unique organizational position and characteristics when determining their desired track selection for PY 1. We seek comment on this proposal and whether there are alternative potential approaches for constructing a glide path in TEAM.

We are also proposing that TEAM participants would be required to notify CMS of their track selection prior to the start of PY 1, in a form and manner and by a date specified by CMS. TEAM participants who fail to timely notify CMS would be automatically assigned to Track 1 for PY 1. We seek comment on the proposal to require TEAM participants to notify CMS of their track selection and to automatically assign TEAM participants to Track 1 if they fail to timely notify CMS of their desired track selection.

The proposed glide path opportunity is limited to one year. We propose that TEAM participants who elected to participate in Track 1 for PY 1 would automatically be assigned to Track 3 for PY 2 and would remain in Track 3 for the remainder of the model (PYs 2 through 5). We recognize that offering different participation tracks in TEAM presents an opportunity to provide flexibilities to TEAM participants that may care for a greater proportion of underserved beneficiaries and TEAM participants that lack the financial reserves to invest in value-based care, including safety net, rural, and other hospital providers. Research has identified APM participation challenges for these types of providers, such as a lack of capital to finance the upfront costs of transitioning to an APM, including purchasing electronic health record technology, and challenges acquiring or conducting data analysis necessary for participation.[588] CMS has taken significant steps to address and improve health equity in value-based care models and programs, including health equity adjustments to the Hospital Value-Based Purchasing Program (88 FR 58640) and the Medicare Shared Savings Program (87 FR 69404).

We are proposing to require different types of hospitals to participate in TEAM, and we believe that certain TEAM participants may benefit from a participation option that has limited two-sided financial risk so that their beneficiaries may receive high quality, coordinated care without imposing significant financial pressure. Therefore, we propose that rather than automatically being assigned to Track 3 beginning in PY 2, certain TEAM participants could elect to participate in Track 2 beginning in PY 2 and stay in Track 2 for the remainder of the model (PYs 2 through 5). As further described in sections X.A.3.d.(5)(h) and X.A.3.d.(5)(g) of the preamble of this proposed rule, we propose that Track 2 would have two-sided financial risk in the form of reconciliation payments and repayment amounts, subject to 10% stop-gain and stop-loss limits, a CQS adjustment percentage of up to 10% for positive reconciliation amounts, and a CQS adjustment percentage of up to 15% for negative reconciliation amounts. We believe the CQS adjustment percentage of up to 15% for negative reconciliation amounts, is appropriate for Track 2 because it further limits a TEAM participant's financial risk given that a higher CQS adjustment percentage for negative reconciliation amounts results in a lower repayment amount. These proposed payments and payment adjustments would allow TEAM participants to receive reconciliation payment amounts or owe repayment amounts based on their quality and cost performance for their episodes.

We propose that only the following types of TEAM participants would be eligible to participate in Track 2 for PYs 2 through 5:

- Hospitals that are safety net hospitals, as further described in section X.A.3.f.(2) of the preamble of this proposed rule. For purposes of TEAM, we propose that a TEAM participant must meet at least one of the following criteria in order to be considered a safety net hospital:

++ Exceeds the 75th percentile of the proportion of Medicare beneficiaries considered dually eligible for Medicare and Medicaid across all PPS acute care hospitals in the baseline period (as described in section X.A.3.d.(3)(a)).

++ Exceeds the 75th percentile of the proportion of Medicare beneficiaries partially or fully eligible to receive Part D low-income subsidies across all PPS acute care hospitals in the baseline period.

- Hospitals that are rural hospitals, as further described in section X.A.3.f.(3) of the preamble of this proposed rule. For purposes of TEAM, we propose that a TEAM participant must meet at least one of the following criteria in order to be considered a rural hospital:

++ Is located in a rural area as defined under § 412.64.

++ Is located in a rural census tract defined under § 412.103(a)(1).

++ Has reclassified as a rural hospital under § 412.103.

++ Is a rural referral center (RRC), which has the same meaning given this term under § 412.96.

- Hospitals that are Medicare dependent hospitals (MDH) as defined under 42 CFR 412.108.
- Hospitals that are sole community hospitals (SCHs) as defined under 42 CFR 412.92.
- Hospitals that are essential access community hospitals as defined under 42 CFR 412.109.

We believe that allowing TEAM participants that meet the safety net hospital or rural hospital criteria, as well as those that are Medicare dependent hospitals, sole community hospitals, or essential access community hospitals to participate in Track 2 during PYs 2 through 5 would provide an opportunity for these hospitals to develop capabilities to deliver value-based care and would avoid the financial pressures of a two-sided financial risk model that could make their participation in TEAM untenable.

We propose that TEAM participants that meet the Track 2 hospital criteria described above would be required to notify CMS on an annual basis prior to the start of every performance year, beginning for PY 2, of their desire to participate in Track 2. We propose that TEAM participants that meet the Track 2 hospital criteria could switch between Track 2 and Track 3 on an annual basis. Such TEAM participants would need to notify CMS of their preference, in a form and manner and by the date specified by CMS. We propose that TEAM participants would need to meet the hospital criteria for Track 2 participation by the date CMS requires notification of their preference. TEAM participants who fail to timely notify CMS or do not meet the Track 2 hospital criteria would not be approved by CMS to participate in Track 2 and would be automatically by assigned to Track 3 for the given performance year. We recognize that allowing these specific TEAM participants to self-select into Track 2 for PYs 2 through 5 could create challenges when evaluating the model, such as the generalizability of evaluation findings. We also recognize

[588] Medicare Information on the Transition to Alternative Payment Models by Providers in Rural, Health Professional Shortage, or Underserved Areas: Report to Congressional Committees. (2021). United States Government Accountability Office. Retrieved December 1, 2023, from *https://www.gao.gov/assets/gao-22-104618.pdf.*

that requiring these specific TEAM participants to notify CMS every year would permit them to switch tracks if they no longer desire to be participate in Track 2 or no longer meet the Track 2 hospital criteria. Therefore, we seek comment on whether we should prohibit TEAM participants from switching tracks after PY2 or if there are other options we should consider to mitigate evaluation challenges.

We considered but are not proposing allowing TEAM participants who meet the safety net hospital criteria to remain in Track 1 for all performance years so that they would not be subject to downside financial risk during their participation in the model. Further, we considered not allowing these TEAM participants who meet the safety net hospital criteria to switch between tracks, meaning that they would have to participate in Track 1 for all performance years. However, we did not want to limit a TEAM participant who meets the safety net hospital criteria from making their own decision about whether to participate in a track with downside financial risk. Further, we believe that having downside risk by PY 2 for all TEAM participants would help to drive care improvements and establish care efficiencies that could lead to better outcomes on cost and quality of care. We seek comment on whether we should consider allowing TEAM participants who meet the safety net hospital criteria to participate in Track 1 for all performance years.

Table X.A.–01 summarizes the proposed TEAM tracks.

TABLE X.A.-01 – SUMMARY OF PROPOSED TEAM PARTICIPATION TRACKS

Track	Performance Year (PY)	TEAM Participant Eligibility	Financial Risk
Track 1	PY 1	All TEAM participants	• Upside risk only (10% stop-gain limit) • CQS adjustment percentage of up to 10% for positive reconciliation amounts
Track 2	PYs 2-5	TEAM participants that meet one of following hospital criteria: • Safety net hospital • Rural hospital • Medicare Dependent Hospital • Sole Community Hospital • Essential Access Community Hospital	• Upside and downside risk (10% stop-gain/stop-loss limits) • CQS adjustment percentage of up to 10% for positive reconciliation amounts and CQS adjustment percentage of up to 15% for negative reconciliation amounts
Track 3	PYs 1-5	All TEAM participants	• Upside and downside risk (20% stop-gain/stop-loss limits) • CQS adjustment percentage of up to 10% for positive and negative reconciliation amounts

We seek comment on the proposals for the TEAM Participation Tracks at § 512.520. We also seek comment on the proposal that TEAM participants who meet the eligibility criteria for Track 2 may self-select into Track 2 and change which track their track selection annually.

(4) Proposed Approach To Select TEAM Participants and Statistical Power

Our proposed participant selection methodology for TEAM is designed to provide adequate statistical power for evaluating and detecting changes in cost and quality.

We are proposing that TEAM would be an episode-based payment model implemented at the hospital level that captures all items and services furnished to a beneficiary over a defined period of time. We are proposing to test five episode categories in TEAM, as described in section X.A.3.b. of the preamble of this proposed rule, focusing on acute clinical procedures initiated in the hospital inpatient and outpatient settings. Specifically, TEAM is proposing to test episodes that begin with CABG, LEJR, major bowel procedure, SHFFT, and spinal fusion. We considered whether the model should be limited to hospitals where a high volume of the proposed five episode categories are performed, which would result in a more narrow test on the effects of an episode-based payment approach, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. Selecting only those hospitals where a high volume of the proposed episode categories are performed may result in fewer hospitals being selected as TEAM participants, but could still result in a sufficient number of episodes to evaluate the success of the model. However, there would be more potential for behaviors that could impact the model test, such as patient shifting and steering between hospitals in a given geographic area.

We propose to select geographic areas and require all hospitals, as defined in section X.A.3.a.(2).(b). of the preamble of this proposed rule, in those selected areas to participate in TEAM to help minimize the risk of TEAM participants shifting higher cost cases to hospitals not participating in TEAM. We propose that, instead of taking a simple random sampling where all geographic areas have the same chance for selection, we would group these geographic areas according to certain characteristics and then randomly select geographic areas from within those groups, also known as strata, for model implementation. Such a stratified random sampling method based on geographic area would provide several benefits. We expect that this method would allow us to observe the experiences of hospitals in geographic areas with various characteristics, such as variations in the number of hospitals, average episode spending, number of hospitals that serve a higher proportion

of historically underserved beneficiaries, and differing experience with previous CMS bundled payment models. We could then examine whether these characteristics impact the effect of the model on patient outcomes and Medicare expenditures within episodes of care. Using a stratified random sampling based on geographic area would also substantially reduce the extent to which the selected hospitals would differ from other hospitals on the characteristics used for stratification, compared to a simple random sample. Simple randomization may ensure similarity between the selected hospitals and hospitals that are not selected, but simple randomization can also lead to differences if enough units are drawn in a group-randomized design where the number of available groups is relatively small,. Finally, using a stratified random sampling of geographic areas would improve the statistical power of the subsequent model evaluation improve our ability to reach conclusions about the model's effects on episode spending and the quality of patient care. Section 1115A(a)(5) of the Act allows the Secretary to limit the testing of a model to certain geographic areas, and we propose for the reasons stated above to use a stratified random sampling method to select geographic areas and require all hospitals within those selected geographic areas to participate in TEAM.

(a) Overview and Options for Geographic Area Selection

We considered using a stratified random sampling methodology to select the following geographic areas: (1) certain counties based on their CBSAs, (2) certain ZIP codes based on their Hospital Referral Regions (HRR) or (3) certain states. We address each geographic unit in turn.

We considered selecting certain counties based on their CBSA. CBSA includes a core area with a substantial portion of the population in adjacent communities having a high degree of economic and social integration with that core. A county is designated as part of a CBSA when the county is associated with at least one core (urbanized area or urban cluster) with a population of at least 10,000, with the adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the other counties associated with the core.

OMB Bulletin 23–01, issued on July 21, 2023, states that there are 935 CBSAs in the United States and Puerto Rico. The 935 CBSAs include 393 Metropolitan Statistical Areas (MSAs), which have an urban core population of at least 50,000, and 542 Micropolitan Statistical Areas (mSAs), which have an urban core population of at least 10,000 but less than 50,000. CBSAs may be further combined into a Combined Statistical Area (CSA) which consists of two or more adjacent CBSAs (including MSAs, mSAs, or both) with substantial employment interchange. Counties not classified as a CBSA are typically categorized and examined at a state level.

The choices for a geographical unit based on CBSA include a CBSA, an MSA, or a CSA. We propose to select CBSAs in this model, which we will discuss later in this section. We note that CJR, a previous mandatory episode-based payment model, utilized MSAs as the geographic unit. Under TEAM, we are proposing to expand upon the CJR model's representation of geographic units by also including smaller geographic units, mSAs, in addition to MSAs. We propose that counties and other areas not located in a CBSA would not be included in the TEAM selection method.

We considered, but ultimately decided against, using CSAs instead of CBSAs as the geographic unit of selection. Under this scenario, we would look at how OMB classifies counties. We would first assess whether a county has been identified as belonging to a CSA, a unit which consists of adjacent CBSAs. If the county was not in a CSA, we would determine if it was in a CBSA that is not part of a larger CSA. Counties not located in a CBSA would be excluded from selection.

We considered a number of factors to decide whether to select geographic areas on the basis of CSAs and CBSAs or just on CBSAs alone, including an assessment of the anticipated degree to which patients who have one of the proposed episode categories would be willing to travel for their initial hospitalization, the extent to which surgeons are expected to have admitting privileges in multiple hospitals located in different CBSAs, and statistical power considerations related to the number of independent geographic units available for selection (there are only 184 CSAs vs. 935 CBSAs). We also considered the risk for patient shifting and steering between CBSAs within a CSA, and we believe that the anticipated risk is not severe enough to warrant selecting CSAs.

We next considered selecting hospital referral regions (HRRs). HRRs represent regional health care markets for tertiary medical care. HRRs are defined by determining where the majority of patients were referred for major cardiovascular surgical procedures and for neurosurgery. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. HRRs may not sufficiently reflect referral patterns for the five episode categories we are proposing to test in TEAM, as only one of the five proposed episode categories is cardiovascular (coronary artery bypass graft surgery), and this episode category has the smallest procedure volume. Therefore, we believe that CBSAs as a geographic unit are preferable over HRRs for this model.

We also considered selecting states as the geographic areas for TEAM. However, we concluded that CBSAs as a geographic unit are preferable over states. Choosing states as the geographic unit would require us to automatically include hospitals in all rural areas within the selected states. Using a unit of selection smaller than a state would allow for a more deliberate choice about the extent of inclusion of rural or small population areas. Selecting states rather than CBSAs would also greatly reduce the number of independent geographic areas subject to selection under the model, which would decrease the statistical power of the model evaluation. Finally, CBSAs straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care. Choosing states as the geographic unit would potentially divide a hospital market and set up a greater potential for patient shifting and steering to different hospitals under the model. CMS decided that the CBSA-level analysis was more analytically appropriate based on the specifics of this model.

For the reasons previously discussed, we propose to require all hospitals, as defined in section X.A.3.a.(2).(b). of the preamble of this proposed rule and in proposed § 512.505, within a CBSA that CMS selects through the stratified random sampling methodology, described in section X.A.3.a.(4).(d). of the preamble of this proposed rule, to participate in TEAM. Although CBSAs are revised periodically, with additional counties added to or removed from certain CBSAs, we propose to use the CBSA designations in OMB Bulletin 23–01 issued on July 21, 2023 as the CBSA designations for purposes of selecting participants for this model, regardless of whether such CBSA designations have changed since July 21, 2023, or will change at some point during the model performance period. We believe that this approach would best maintain the consistency of the TEAM participants in

the model, which is crucial for our ability to evaluate the effects of the model test on quality of care and changes in Medicare spending.

(b) Exclusion of Certain CBSAs

We propose to exclude from the stratified random sampling of geographic areas any CBSAs that are located entirely in the state of Maryland, and certain CBSAs that straddle Maryland and another state. If a CBSA: (1) includes a portion of Maryland; and (2) more than 50 percent of the episodes that initiated at hospitals within that CBSA between January 1, 2022 and June 30, 2023 for any of the five episode categories proposed for testing in TEAM did so at hospitals in Maryland, that CBSA will also be excluded from TEAM. We are proposing to exclude these CBSAs from selection because the state of Maryland is currently participating in another Innovation Center Model—the Maryland Total Cost Of Care Model, as further described in section X.A.3.a.(2).(b).(i). of the preamble of this proposed rule.

We also propose to exclude CBSAs in which no episodes were initiated at hospitals for any of the five episode categories proposed for testing in TEAM between January 1, 2022 and June 30, 2023. We believe it will be highly unlikely for these CBSAs to have data available for evaluation after the model starts. After applying these criteria, 803 CBSAs remain available for selection in TEAM. We propose to use a stratified random sampling method as described below to select approximately 25 percent of eligible CBSAs in TEAM following the process we describe in the next two sections. We are providing the proposed list of CBSAs eligible for selection in TEAM in Table X.A.–02.[589]

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[589] This list was generated using the criteria and methods that are being proposed, and is subject to change if different criteria and methods end up being finalized.

TABLE X.A.-02: LIST OF CBSAs ELIGIBLE FOR SELCTION IN TEAM

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
10100	Aberdeen, SD	7
10140	Aberdeen, WA	1
10180	Abilene, TX	6
10220	Ada, OK	4
10300	Adrian, MI	5
10380	Aguadilla, PR	3
10420	Akron, OH	8
10460	Alamogordo, NM	5
10480	Alamosa, CO	9
10500	Albany, GA	2
10540	Albany, OR	1
10580	Albany-Schenectady-Troy, NY	4
10620	Albemarle, NC	1
10660	Albert Lea, MN	1
10700	Albertville, AL	5
10740	Albuquerque, NM	16
10760	Alexander City, AL	1
10780	Alexandria, LA	16
10820	Alexandria, MN	1
10860	Alice, TX	14
10900	Allentown-Bethlehem-Easton, PA-NJ	8
10940	Alma, MI	5
10980	Alpena, MI	5
11020	Altoona, PA	4
11060	Altus, OK	2
11100	Amarillo, TX	8
11140	Americus, GA	1
11180	Ames, IA	1
11200	Amherst Town-Northampton, MA	1
11220	Amsterdam, NY	14
11260	Anchorage, AK	16
11360	Anderson Creek, NC	1
11460	Ann Arbor, MI	8
11500	Anniston-Oxford, AL	6
11540	Appleton, WI	7
11580	Arcadia, FL	1
11620	Ardmore, OK	2
11640	Arecibo, PR	3
11680	Arkansas City-Winfield, KS	1
11700	Asheville, NC	8
11740	Ashland, OH	5
11900	Athens, OH	5
11940	Athens, TN	5
11980	Athens, TX	5
12020	Athens-Clarke County, GA	8
12060	Atlanta-Sandy Springs-Roswell, GA	12
12100	Atlantic City-Hammonton, NJ	8
12140	Auburn, IN	1
12180	Auburn, NY	1
12220	Auburn-Opelika, AL	1
12260	Augusta-Richmond County, GA-SC	8
12300	Augusta-Waterville, ME	11
12420	Austin-Round Rock-San Marcos, TX	8
12460	Bainbridge, GA	1
12540	Bakersfield-Delano, CA	16

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
12620	Bangor, ME	16
12660	Baraboo, WI	3
12700	Barnstable Town, MA	4
12740	Barre, VT	1
12780	Bartlesville, OK	6
12860	Batavia, NY	5
12900	Batesville, AR	2
12940	Baton Rouge, LA	16
12980	Battle Creek, MI	3
13020	Bay City, MI	2
13060	Bay City, TX	6
13140	Beaumont-Port Arthur, TX	8
13180	Beaver Dam, WI	7
13220	Beckley, WV	4
13300	Beeville, TX	2
13340	Bellefontaine, OH	1
13380	Bellingham, WA	5
13420	Bemidji, MN	1
13460	Bend, OR	4
13540	Bennington, VT	1
13660	Big Rapids, MI	1
13700	Big Spring, TX	1
13740	Billings, MT	8
13780	Binghamton, NY	8
13820	Birmingham, AL	4
13900	Bismarck, ND	3
13940	Blackfoot, ID	1
13980	Blacksburg-Christiansburg-Radford, VA	7
14010	Bloomington, IL	7
14020	Bloomington, IN	4
14100	Bloomsburg-Berwick, PA	3
14140	Bluefield, WV-VA	3
14180	Blytheville, AR	9
14220	Bogalusa, LA	10
14260	Boise City, ID	7
14380	Boone, NC	5
14460	Boston-Cambridge-Newton, MA-NH	16
14500	Boulder, CO	8
14540	Bowling Green, KY	8
14580	Bozeman, MT	5
14620	Bradford, PA	1
14660	Brainerd, MN	1
14700	Branson, MO	1
14710	Brattleboro, VT	1
14720	Breckenridge, CO	1
14740	Bremerton-Silverdale-Port Orchard, WA	6
14860	Bridgeport-Stamford-Danbury, CT	8
14940	Brigham City, UT-ID	7
15020	Brookhaven, MS	1
15100	Brookings, SD	1
15180	Brownsville-Harlingen, TX	16
15220	Brownwood, TX	2
15260	Brunswick-St. Simons, GA	2
15380	Buffalo-Cheektowaga, NY	16
15460	Burlington, IA-IL	1
15500	Burlington, NC	5
15540	Burlington-South Burlington, VT	4

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
15580	Butte-Silver Bow, MT	6
15620	Cadillac, MI	5
15660	Calhoun, GA	5
15740	Cambridge, OH	1
15780	Camden, AR	5
15820	Campbellsville, KY	1
15900	Canton, IL	1
15940	Canton-Massillon, OH	8
15980	Cape Coral-Fort Myers, FL	16
16020	Cape Girardeau, MO-IL	4
16060	Carbondale, IL	2
16100	Carlsbad-Artesia, NM	7
16140	Carroll, IA	5
16180	Carson City, NV	5
16220	Casper, WY	8
16260	Cedar City, UT	5
16300	Cedar Rapids, IA	7
16380	Celina, OH	1
16460	Centralia, IL	9
16500	Centralia, WA	5
16540	Chambersburg, PA	7
16580	Champaign-Urbana, IL	4
16620	Charleston, WV	3
16660	Charleston-Mattoon, IL	5
16700	Charleston-North Charleston, SC	4
16740	Charlotte-Concord-Gastonia, NC-SC	8
16820	Charlottesville, VA	8
16860	Chattanooga, TN-GA	4
16940	Cheyenne, WY	1
16980	Chicago-Naperville-Elgin, IL-IN	17
17020	Chico, CA	12
17060	Chillicothe, OH	2
17140	Cincinnati, OH-KY-IN	8
17220	Clarksburg, WV	1
17260	Clarksdale, MS	10
17300	Clarksville, TN-KY	7
17380	Cleveland, MS	14
17410	Cleveland, OH	16
17420	Cleveland, TN	5
17540	Clinton, IA	5
17580	Clovis, NM	7
17660	Coeur d'Alene, ID	4
17740	Coldwater, MI	1
17780	College Station-Bryan, TX	8
17820	Colorado Springs, CO	4
17860	Columbia, MO	8
17900	Columbia, SC	4
17980	Columbus, GA-AL	8
18020	Columbus, IN	5
18060	Columbus, MS	14
18100	Columbus, NE	1
18140	Columbus, OH	8
18180	Concord, NH	6
18260	Cookeville, TN	16
18300	Coos Bay-North Bend, OR	1
18340	Corbin, KY	16
18380	Cordele, GA	1

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
18420	Corinth, MS	6
18460	Cornelia, GA	1
18500	Corning, NY	7
18580	Corpus Christi, TX	8
18620	Corsicana, TX	5
18660	Cortland, NY	1
18700	Corvallis, OR	1
18740	Coshocton, OH	5
18820	Crawfordsville, IN	5
18860	Crescent City, CA	5
18880	Crestview-Fort Walton Beach-Destin, FL	4
18900	Crossville, TN	5
18980	Cullman, AL	5
19100	Dallas-Fort Worth-Arlington, TX	16
19140	Dalton, GA	1
19180	Danville, IL	1
19220	Danville, KY	6
19260	Danville, VA	6
19300	Daphne-Fairhope-Foley, AL	3
19340	Davenport-Moline-Rock Island, IA-IL	7
19430	Dayton-Kettering-Beavercreek, OH	8
19460	Decatur, AL	1
19500	Decatur, IL	3
19580	Defiance, OH	1
19620	Del Rio, TX	13
19660	Deltona-Daytona Beach-Ormond Beach, FL	8
19740	Denver-Aurora-Centennial, CO	16
19760	DeRidder, LA	2
19780	Des Moines-West Des Moines, IA	16
19810	Detroit Lakes, MN	1
19820	Detroit-Warren-Dearborn, MI	16
19940	Dixon, IL	1
19980	Dodge City, KS	5
20020	Dothan, AL	8
20060	Douglas, GA	1
20100	Dover, DE	6
20140	Dublin, GA	6
20180	DuBois, PA	1
20220	Dubuque, IA	7
20260	Duluth, MN-WI	3
20340	Duncan, OK	1
20420	Durango, CO	3
20460	Durant, OK	14
20500	Durham-Chapel Hill, NC	4
20540	Dyersburg, TN	6
20580	Eagle Pass, TX	14
20700	East Stroudsburg, PA	7
20740	Eau Claire, WI	11
20780	Edwards, CO	1
20820	Effingham, IL	5
20940	El Centro, CA	15
20980	El Dorado, AR	6
21020	Elizabeth City, NC	5
21060	Elizabethtown, KY	2
21120	Elk City, OK	1
21140	Elkhart-Goshen, IN	8
21180	Elkins, WV	1

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
21220	Elko, NV	5
21300	Elmira, NY	5
21340	El Paso, TX	8
21420	Enid, OK	8
21460	Enterprise, AL	5
21500	Erie, PA	12
21580	Española, NM	1
21660	Eugene-Springfield, OR	3
21700	Eureka-Arcata, CA	3
21740	Evanston, WY-UT	1
21780	Evansville, IN	8
21820	Fairbanks-College, AK	1
21860	Fairmont, MN	1
22020	Fargo, ND-MN	4
22060	Faribault-Northfield, MN	1
22100	Farmington, MO	5
22140	Farmington, NM	11
22180	Fayetteville, NC	7
22190	Fayetteville, TN	5
22220	Fayetteville-Springdale-Rogers, AR	8
22260	Fergus Falls, MN	1
22300	Findlay, OH	5
22340	Fitzgerald, GA	1
22380	Flagstaff, AZ	16
22420	Flint, MI	16
22500	Florence, SC	4
22520	Florence-Muscle Shoals, AL	4
22540	Fond du Lac, WI	1
22580	Forest City, NC	5
22620	Forrest City, AR	9
22660	Fort Collins-Loveland, CO	8
22700	Fort Dodge, IA	1
22820	Fort Morgan, CO	1
22840	Fort Payne, AL	5
22900	Fort Smith, AR-OK	8
23060	Fort Wayne, IN	16
23180	Frankfort, KY	1
23240	Fredericksburg, TX	5
23300	Freeport, IL	1
23340	Fremont, NE	1
23380	Fremont, OH	3
23420	Fresno, CA	16
23460	Gadsden, AL	8
23500	Gaffney, SC	1
23540	Gainesville, FL	8
23580	Gainesville, GA	2
23620	Gainesville, TX	6
23660	Galesburg, IL	1
23680	Gallipolis, OH	2
23700	Gallup, NM	11
23780	Garden City, KS	2
23900	Gettysburg, PA	5
23940	Gillette, WY	1
23980	Glasgow, KY	1
24020	Glens Falls, NY	1
24100	Gloversville, NY	13
24140	Goldsboro, NC	1

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
24180	Granbury, TX	6
24220	Grand Forks, ND-MN	2
24260	Grand Island, NE	6
24300	Grand Junction, CO	8
24330	Grand Rapids, MN	1
24340	Grand Rapids-Wyoming-Kentwood, MI	8
24420	Grants Pass, OR	5
24460	Great Bend, KS	1
24500	Great Falls, MT	7
24540	Greeley, CO	8
24580	Green Bay, WI	4
24620	Greeneville, TN	5
24640	Greenfield, MA	9
24660	Greensboro-High Point, NC	3
24740	Greenville, MS	10
24780	Greenville, NC	2
24820	Greenville, OH	1
24860	Greenville-Anderson-Greer, SC	4
24900	Greenwood, MS	14
24940	Greenwood, SC	6
24980	Grenada, MS	10
25060	Gulfport-Biloxi, MS	8
25220	Hammond, LA	12
25260	Hanford-Corcoran, CA	13
25300	Hannibal, MO	1
25420	Harrisburg-Carlisle, PA	8
25460	Harrison, AR	1
25500	Harrisonburg, VA	5
25540	Hartford-West Hartford-East Hartford, CT	16
25580	Hastings, NE	1
25620	Hattiesburg, MS	8
25700	Hays, KS	2
25720	Heber, UT	5
25740	Helena, MT	1
25775	Henderson, KY	2
25780	Henderson, NC	13
25850	Hermitage, PA	3
25860	Hickory-Lenoir-Morganton, NC	7
25880	Hillsdale, MI	5
25900	Hilo-Kailua, HI	7
25940	Hilton Head Island-Bluffton-Port Royal, SC	3
26020	Hobbs, NM	13
26140	Homosassa Springs, FL	7
26300	Hot Springs, AR	4
26340	Houghton, MI	1
26380	Houma-Bayou Cane-Thibodaux, LA	12
26420	Houston-Pasadena-The Woodlands, TX	16
26460	Hudson, NY	5
26500	Huntingdon, PA	1
26540	Huntington, IN	1
26580	Huntington-Ashland, WV-KY-OH	12
26620	Huntsville, AL	8
26660	Huntsville, TX	1
26740	Hutchinson, KS	3
26780	Hutchinson, MN	1
26820	Idaho Falls, ID	6
26860	Indiana, PA	5

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
26900	Indianapolis-Carmel-Greenwood, IN	12
26980	Iowa City, IA	4
27020	Iron Mountain, MI-WI	5
27060	Ithaca, NY	1
27100	Jackson, MI	5
27140	Jackson, MS	16
27180	Jackson, TN	8
27220	Jackson, WY-ID	1
27260	Jacksonville, FL	8
27300	Jacksonville, IL	5
27340	Jacksonville, NC	5
27380	Jacksonville, TX	1
27460	Jamestown-Dunkirk, NY	3
27500	Janesville-Beloit, WI	3
27540	Jasper, IN	1
27620	Jefferson City, MO	7
27700	Jesup, GA	1
27740	Johnson City, TN	8
27780	Johnstown, PA	6
27860	Jonesboro, AR	6
27900	Joplin, MO-KS	4
27940	Juneau, AK	1
27980	Kahului-Wailuku, HI	1
28020	Kalamazoo-Portage, MI	8
28060	Kalispell, MT	1
28100	Kankakee, IL	8
28140	Kansas City, MO-KS	16
28180	Kapaa, HI	1
28260	Kearney, NE	8
28300	Keene, NH	1
28340	Kendallville, IN	1
28420	Kennewick-Richland, WA	7
28450	Kenosha, WI	7
28500	Kerrville, TX	5
28580	Key West-Key Largo, FL	1
28660	Killeen-Temple, TX	8
28680	Kingsland, GA	5
28700	Kingsport-Bristol, TN-VA	4
28740	Kingston, NY	2
28780	Kingsville, TX	10
28820	Kinston, NC	9
28860	Kirksville, MO	6
28880	Kiryas Joel-Poughkeepsie-Newburgh, NY	4
28900	Klamath Falls, OR	1
28940	Knoxville, TN	8
29020	Kokomo, IN	7
29060	Laconia, NH	1
29100	La Crosse-Onalaska, WI-MN	4
29180	Lafayette, LA	16
29200	Lafayette-West Lafayette, IN	8
29300	LaGrange, GA-AL	2
29340	Lake Charles, LA	8
29380	Lake City, FL	5
29420	Lake Havasu City-Kingman, AZ	7
29460	Lakeland-Winter Haven, FL	8
29540	Lancaster, PA	8
29620	Lansing-East Lansing, MI	4

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
29660	Laramie, WY	1
29700	Laredo, TX	16
29740	Las Cruces, NM	4
29780	Las Vegas, NM	9
29820	Las Vegas-Henderson-North Las Vegas, NV	16
29860	Laurel, MS	1
29900	Laurinburg, NC	1
29940	Lawrence, KS	1
29980	Lawrenceburg, TN	1
30020	Lawton, OK	4
30060	Lebanon, MO	1
30140	Lebanon, PA	5
30150	Lebanon-Claremont, NH-VT	2
30260	Lewisburg, PA	1
30300	Lewiston, ID-WA	6
30340	Lewiston-Auburn, ME	16
30380	Lewistown, PA	5
30460	Lexington-Fayette, KY	8
30580	Liberal, KS	2
30620	Lima, OH	8
30700	Lincoln, NE	8
30780	Little Rock-North Little Rock-Conway, AR	8
30860	Logan, UT-ID	7
30900	Logansport, IN	1
30980	Longview, TX	4
31020	Longview-Kelso, WA	1
31060	Los Alamos, NM	1
31080	Los Angeles-Long Beach-Anaheim, CA	17
31140	Louisville/Jefferson County, KY-IN	4
31180	Lubbock, TX	8
31220	Ludington, MI	5
31260	Lufkin, TX	8
31300	Lumberton, NC	9
31340	Lynchburg, VA	6
31380	Macomb, IL	1
31420	Macon-Bibb County, GA	8
31500	Madison, IN	1
31540	Madison, WI	4
31580	Madisonville, KY	5
31620	Magnolia, AR	1
31700	Manchester-Nashua, NH	4
31740	Manhattan, KS	3
31820	Manitowoc, WI	7
31860	Mankato, MN	1
31900	Mansfield, OH	8
31930	Marietta, OH	2
31940	Marinette, WI-MI	5
31980	Marion, IN	5
32000	Marion, NC	1
32020	Marion, OH	1
32060	Marion-Herrin, IL	7
32100	Marquette, MI	6
32180	Marshall, MO	5
32260	Marshalltown, IA	5
32280	Martin, TN	5
32340	Maryville, MO	1
32380	Mason City, IA	6

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
32390	Massena-Ogdensburg, NY	11
32420	Mayagüez, PR	3
32460	Mayfield, KY	6
32540	McAlester, OK	1
32580	McAllen-Edinburg-Mission, TX	16
32620	McComb, MS	10
32660	McMinnville, TN	5
32700	McPherson, KS	1
32740	Meadville, PA	1
32780	Medford, OR	4
32820	Memphis, TN-MS-AR	16
32900	Merced, CA	15
32940	Meridian, MS	4
33060	Miami, OK	5
33100	Miami-Fort Lauderdale-West Palm Beach, FL	17
33140	Michigan City-La Porte, IN	8
33180	Middlesborough, KY	13
33220	Midland, MI	6
33260	Midland, TX	6
33300	Milledgeville, GA	1
33340	Milwaukee-Waukesha, WI	15
33380	Minden, LA	10
33420	Mineral Wells, TX	1
33460	Minneapolis-St. Paul-Bloomington, MN-WI	12
33500	Minot, ND	1
33540	Missoula, MT	8
33580	Mitchell, SD	1
33620	Moberly, MO	5
33660	Mobile, AL	8
33700	Modesto, CA	16
33740	Monroe, LA	16
33780	Monroe, MI	1
33860	Montgomery, AL	8
33910	Monticello, NY	10
33940	Montrose, CO	1
33980	Morehead City, NC	5
34020	Morgan City, LA	2
34060	Morgantown, WV	4
34100	Morristown, TN	7
34180	Moses Lake, WA	1
34220	Moultrie, GA	1
34260	Mountain Home, AR	1
34340	Mount Airy, NC	3
34380	Mount Pleasant, MI	5
34420	Mount Pleasant, TX	1
34460	Mount Sterling, KY	5
34500	Mount Vernon, IL	3
34540	Mount Vernon, OH	1
34580	Mount Vernon-Anacortes, WA	7
34620	Muncie, IN	2
34660	Murray, KY	1
34680	Murrells Inlet, SC	7
34700	Muscatine, IA	1
34740	Muskegon-Norton Shores, MI	6
34780	Muskogee, OK	2
34820	Myrtle Beach-Conway-North Myrtle Beach, SC	4
34860	Nacogdoches, TX	8

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
34900	Napa, CA	8
34940	Naples-Marco Island, FL	8
34980	Nashville-Davidson--Murfreesboro--Franklin, TN	16
35020	Natchez, MS-LA	14
35060	Natchitoches, LA	2
35100	New Bern, NC	5
35140	Newberry, SC	1
35220	New Castle, IN	1
35300	New Haven, CT	16
35340	New Iberia, LA	6
35380	New Orleans-Metairie, LA	16
35420	New Philadelphia-Dover, OH	5
35460	Newport, TN	5
35620	New York-Newark-Jersey City, NY-NJ	17
35660	Niles, MI	3
35740	Norfolk, NE	2
35820	North Platte, NE	1
35840	North Port-Bradenton-Sarasota, FL	8
35900	North Wilkesboro, NC	1
35940	Norwalk, OH	5
35980	Norwich-New London-Willimantic, CT	15
36100	Ocala, FL	8
36220	Odessa, TX	4
36260	Ogden, UT	8
36340	Oil City, PA	1
36380	Okeechobee, FL	1
36420	Oklahoma City, OK	8
36460	Olean, NY	1
36500	Olympia-Lacey-Tumwater, WA	8
36540	Omaha, NE-IA	8
36580	Oneonta, NY	4
36620	Ontario, OR-ID	5
36660	Opelousas, LA	14
36700	Orangeburg, SC	6
36740	Orlando-Kissimmee-Sanford, FL	16
36780	Oshkosh-Neenah, WI	7
36837	Ottawa, IL	3
36840	Ottawa, KS	1
36900	Ottumwa, IA	2
36940	Owatonna, MN	1
36980	Owensboro, KY	1
37020	Owosso, MI	1
37060	Oxford, MS	6
37100	Oxnard-Thousand Oaks-Ventura, CA	16
37120	Ozark, AL	1
37140	Paducah, KY-IL	8
37260	Palatka, FL	6
37300	Palestine, TX	6
37340	Palm Bay-Melbourne-Titusville, FL	8
37420	Pampa, TX	1
37460	Panama City-Panama City Beach, FL	8
37500	Paragould, AR	5
37540	Paris, TN	5
37580	Paris, TX	6
37620	Parkersburg-Vienna, WV	2
37860	Pensacola-Ferry Pass-Brent, FL	8
37900	Peoria, IL	3

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
37950	Petoskey, MI	6
37980	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	16
38060	Phoenix-Mesa-Chandler, AZ	16
38100	Picayune, MS	1
38180	Pierre, SD	1
38210	Pikeville, KY	12
38220	Pine Bluff, AR	6
38240	Pinehurst-Southern Pines, NC	5
38260	Pittsburg, KS	1
38300	Pittsburgh, PA	4
38340	Pittsfield, MA	2
38380	Plainview, TX	6
38460	Plattsburgh, NY	1
38500	Plymouth, IN	5
38540	Pocatello, ID	2
38620	Ponca City, OK	5
38660	Ponce, PR	3
38700	Pontiac, IL	1
38740	Poplar Bluff, MO	14
38820	Port Angeles, WA	1
38860	Portland-South Portland, ME	4
38900	Portland-Vancouver-Hillsboro, OR-WA	15
38940	Port St. Lucie, FL	8
39020	Portsmouth, OH	11
39060	Pottsville, PA	7
39150	Prescott Valley-Prescott, AZ	3
39220	Price, UT	5
39300	Providence-Warwick, RI-MA	15
39340	Provo-Orem-Lehi, UT	8
39380	Pueblo, CO	8
39460	Punta Gorda, FL	8
39480	Putnam, CT	11
39500	Quincy, IL-MO	6
39540	Racine-Mount Pleasant, WI	7
39580	Raleigh-Cary, NC	3
39660	Rapid City, SD	7
39740	Reading, PA	7
39780	Red Bluff, CA	13
39820	Redding, CA	16
39860	Red Wing, MN	1
39900	Reno, NV	8
39940	Rexburg, ID	1
39960	Rice Lake, WI	1
39980	Richmond, IN	2
40060	Richmond, VA	8
40080	Richmond-Berea, KY	11
40090	Rifle, CO	2
40140	Riverside-San Bernardino-Ontario, CA	17
40180	Riverton, WY	1
40220	Roanoke, VA	8
40260	Roanoke Rapids, NC	5
40340	Rochester, MN	4
40380	Rochester, NY	11
40420	Rockford, IL	8
40540	Rock Springs, WY	1
40580	Rocky Mount, NC	15
40620	Rolla, MO	6

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
40660	Rome, GA	4
40700	Roseburg, OR	5
40740	Roswell, NM	15
40770	Russellville, AL	9
40780	Russellville, AR	6
40820	Ruston, LA	6
40860	Rutland, VT	1
40900	Sacramento-Roseville-Folsom, CA	16
40980	Saginaw, MI	4
41060	St. Cloud, MN	2
41100	St. George, UT	6
41140	St. Joseph, MO-KS	6
41180	St. Louis, MO-IL	16
41400	Salem, OH	7
41420	Salem, OR	3
41460	Salina, KS	4
41500	Salinas, CA	16
41620	Salt Lake City-Murray, UT	8
41660	San Angelo, TX	2
41700	San Antonio-New Braunfels, TX	16
41740	San Diego-Chula Vista-Carlsbad, CA	16
41780	Sandusky, OH	1
41820	Sanford, NC	5
41860	San Francisco-Oakland-Fremont, CA	17
41940	San Jose-Sunnyvale-Santa Clara, CA	16
41980	San Juan-Bayamón-Caguas, PR	3
42020	San Luis Obispo-Paso Robles, CA	8
42100	Santa Cruz-Watsonville, CA	16
42140	Santa Fe, NM	3
42200	Santa Maria-Santa Barbara, CA	12
42220	Santa Rosa-Petaluma, CA	16
42300	Sault Ste. Marie, MI	1
42340	Savannah, GA	4
42380	Sayre, PA	6
42420	Scottsbluff, NE	2
42460	Scottsboro, AL	1
42540	Scranton--Wilkes-Barre, PA	8
42580	Seaford, DE	7
42620	Searcy, AR	2
42660	Seattle-Tacoma-Bellevue, WA	16
42680	Sebastian-Vero Beach-West Vero Corridor, FL	8
42700	Sebring, FL	8
42740	Sedalia, MO	1
42820	Selma, AL	9
42860	Seneca, SC	2
42940	Sevierville, TN	5
42980	Seymour, IN	1
43060	Shawnee, OK	2
43100	Sheboygan, WI	3
43140	Shelby-Kings Mountain, NC	1
43180	Shelbyville, TN	5
43260	Sheridan, WY	1
43300	Sherman-Denison, TX	8
43320	Show Low, AZ	5
43340	Shreveport-Bossier City, LA	16
43380	Sidney, OH	5
43420	Sierra Vista-Douglas, AZ	5

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
43580	Sioux City, IA-NE-SD	7
43620	Sioux Falls, SD-MN	3
43640	Slidell-Mandeville-Covington, LA	8
43700	Somerset, KY	13
43740	Somerset, PA	7
43760	Sonora, CA	6
43780	South Bend-Mishawaka, IN-MI	7
43900	Spartanburg, SC	2
43940	Spearfish, SD	1
43980	Spencer, IA	1
44020	Spirit Lake, IA	1
44060	Spokane-Spokane Valley, WA	8
44100	Springfield, IL	4
44140	Springfield, MA	16
44180	Springfield, MO	4
44220	Springfield, OH	8
44260	Starkville, MS	2
44300	State College, PA	2
44340	Statesboro, GA	2
44420	Staunton-Stuarts Draft, VA	5
44460	Steamboat Springs, CO	1
44500	Stephenville, TX	1
44540	Sterling, CO	1
44580	Sterling, IL	1
44620	Stevens Point-Plover, WI	1
44660	Stillwater, OK	2
44700	Stockton-Lodi, CA	16
44780	Sturgis, MI	3
44860	Sulphur Springs, TX	2
44900	Summerville, GA	1
44940	Sumter, SC	1
44980	Sunbury, PA	6
45020	Sweetwater, TX	1
45060	Syracuse, NY	8
45140	Tahlequah, OK	4
45180	Talladega-Sylacauga, AL	11
45220	Tallahassee, FL	16
45300	Tampa-St. Petersburg-Clearwater, FL	16
45460	Terre Haute, IN	8
45500	Texarkana, TX-AR	8
45520	The Dalles, OR	1
45580	Thomaston, GA	1
45620	Thomasville, GA	2
45660	Tiffin, OH	1
45700	Tifton, GA	1
45740	Toccoa, GA	1
45780	Toledo, OH	8
45820	Topeka, KS	8
45860	Torrington, CT	11
45900	Traverse City, MI	6
45940	Trenton-Princeton, NJ	16
45980	Troy, AL	1
46020	Truckee-Grass Valley, CA	5
46060	Tucson, AZ	8
46100	Tullahoma-Manchester, TN	5
46140	Tulsa, OK	16
46180	Tupelo, MS	12

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
46220	Tuscaloosa, AL	1
46300	Twin Falls, ID	1
46340	Tyler, TX	8
46380	Ukiah, CA	1
46460	Union City, TN	6
46520	Urban Honolulu, HI	4
46540	Utica-Rome, NY	4
46660	Valdosta, GA	2
46700	Vallejo, CA	15
46780	Van Wert, OH	5
46860	Vernal, UT	5
46900	Vernon, TX	1
46980	Vicksburg, MS	2
47020	Victoria, TX	4
47080	Vidalia, GA	5
47180	Vincennes, IN	2
47220	Vineland, NJ	2
47260	Virginia Beach-Chesapeake-Norfolk, VA-NC	7
47300	Visalia, CA	12
47380	Waco, TX	8
47460	Walla Walla, WA	5
47540	Wapakoneta, OH	1
47580	Warner Robins, GA	3
47620	Warren, PA	5
47660	Warrensburg, MO	1
47700	Warsaw, IN	5
47780	Washington, IN	2
47900	Washington-Arlington-Alexandria, DC-VA-MD-WV	12
47940	Waterloo-Cedar Falls, IA	3
47980	Watertown, SD	1
48020	Watertown-Fort Atkinson, WI	1
48060	Watertown-Fort Drum, NY	1
48140	Wausau, WI	4
48180	Waycross, GA	2
48200	Waynesville, NC	5
48260	Weirton-Steubenville, WV-OH	8
48300	Wenatchee-East Wenatchee, WA	3
48460	West Plains, MO	5
48540	Wheeling, WV-OH	4
48580	Whitewater-Elkhorn, WI	5
48620	Wichita, KS	8
48660	Wichita Falls, TX	4
48680	Wildwood-The Villages, FL	6
48700	Williamsport, PA	2
48820	Willmar, MN	1
48900	Wilmington, NC	4
48940	Wilmington, OH	1
48980	Wilson, NC	5
49010	Winchester, TN	5
49020	Winchester, VA-WV	5
49100	Winona, MN	1
49180	Winston-Salem, NC	4
49220	Wisconsin Rapids-Marshfield, WI	4
49260	Woodward, OK	1
49300	Wooster, OH	1
49340	Worcester, MA	12
49380	Worthington, MN	1

OMB CBSA 2023 Code	Metropolitan or Micropolitan Statistical Area Title	TEAM Sample Stratum Number
49420	Yakima, WA	3
49460	Yankton, SD	1
49620	York-Hanover, PA	7
49660	Youngstown-Warren, OH	8
49700	Yuba City, CA	12
49740	Yuma, AZ	2
49780	Zanesville, OH	6

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(c) Selection Strata

We propose to stratify CBSAs into groups based on average historical episode spending, the number of hospitals, the number of safety net hospitals, and the CBSA's exposure to prior CMS bundled payment models.

Stratification enables certain groups of interest to be represented at a higher level, or oversampled, in the model test. One of CMS' policy objectives is to extend the reach of value-based care to more beneficiaries, including beneficiaries from underserved communities. Consistent with that objective, CMS proposes to oversample CBSAs that have limited previous exposure to CMS' bundled payment models and CBSAs with a higher number of safety net hospitals.

We considered stratifying eligible CBSAs into mutually exclusive groups corresponding to the 16 unique combinations of ''high'' and ''low'' values for the following four CBSA-level characteristics (based on the median values across all CBSAs):

• *Average spend for a broad set of episode categories in the CBSA.* There are significant healthcare cost differences across geographic regions. One of the main objectives of TEAM is to reduce episode spending, and the proposed pricing methodology for episodes is regional. Thus, it will be important for the TEAM design to account for the significant variation in average episode spending across geographic regions. We propose to use the episode categories included in the predecessor bundled payment model, BPCI Advanced, initiated between January 1, 2022 and June 30, 2023 to determine the average spend for broad set of episode categories for each CBSA. The episode categories are: Acute myocardial infarction; Cardiac arrhythmia; Congestive heart failure; Cardiac defibrillator; Cardiac valve; Coronary artery bypass graft; Endovascular cardiac valve replacement; Pacemaker; Percutaneous coronary intervention; Cardiac defibrillator; Percutaneous coronary intervention; Disorders of liver except malignancy; cirrhosis or alcoholic hepatitis; Gastrointestinal hemorrhage; Gastrointestinal obstruction; Inflammatory bowel disease; Bariatric surgery; Major bowel procedure; Cellulitis; Chronic obstructive pulmonary disease; bronchitis, asthma, Renal failure; Sepsis; Simple pneumonia and respiratory infections; Urinary tract infection; Seizures; Stroke; Double joint replacement of the lower extremity; Fractures of the femur and hip or pelvis; Hip & femur procedures except major joint; Lower extremity and humerus procedure except hip, foot, femur; Major joint replacement of the lower extremity; Major joint replacement of the upper extremity; Back & neck except spinal fusion; Spinal fusion; Back & neck except spinal fusion. [590]

• *Number of hospitals within the CBSA.* We are proposing to select CBSAs for purposes of model implementation, which include mSA areas in addition to MSAs, meaning that TEAM would be highly representative of the United States and would include many areas with only a single hospital as well as areas with a high number of hospitals. We expect significant differences in the healthcare environment and beneficiary characteristics across CBSAs with low and high numbers of hospitals. Consequently, we believe it is important to select areas above and below the median to have broad representation of CBSAs included in the model.

• *CBSA's past exposure to CMS' bundled payment models* (BPCI Models 2, 3, and 4, CJR, or BPCI Advanced) during the period from October 1, 2013 to December 31, 2022. The extent of previous participation in bundled payment models in a CBSA may be a factor in how successful TEAM participants will be at reducing costs and improving quality of care under the model. This stratification will allow CMS to assess how TEAM's impacts vary by past regional exposure to bundled payment models.

• *Number of safety net hospitals in the CBSA.* Safety net providers have historically not participated in voluntary episode-based payment models as frequently as other providers. Through TEAM, we see an opportunity to improve care for beneficiaries served by safety net providers and want to ensure focus on care redesign and improving quality of care for beneficiaries in underserved communities, consistent with CMS' objectives to improve health equity. Stratifying CBSAs by the number of safety net hospitals will allow CMS to gather robust data to assess TEAM's effects across a range of provider types.

We ultimately decided to create an additional stratum from one of these 16 strata for a total of 17 strata to select CBSAs into TEAM. Below, we identify the stratum we propose to split into two strata and how we would do that; and describe the reasons for this decision.

We note that there are only a handful of outlier CBSAs with a very high number of safety net hospitals. Inclusion of these outlier CBSAs result in an extremely lopsided or asymmetrical distribution when stratifying CBSAs by this characteristic. Depending on the circumstances, these handful of CBSAs may potentially lead to significant differences in the total number of safety net hospitals between the CBSAs that are selected for TEAM and those that are not selected. We therefore propose to move these CBSAs into a new 17th stratum. The proposed stratification process would result in 17 mutually exclusive strata of CBSAs.

(d) Random Selection of CBSAs from Strata

We propose to randomly select CBSAs for TEAM from the 17 stratified groups using a method that reflects CMS' policy objectives described above, including expanding the reach of value-based care. We propose to oversample CBSAs with low past exposure to CMS' bundled payment models and CBSAs with a high number of safety net hospitals. The selection probability for a given CBSA would differ across strata, but all CBSAs

[590] See the technical resources section of the following web page on how these episode categories were constructed: *https://www.cms.gov/priorities/innovation/innovation-models/bpci-advanced/participant-resources.*

within a particular stratum, will have the same chance of being selected. The hospitals located in the selected CBSAs will be required to participate. CMS' proposed method of randomly selecting CBSAs while oversampling CBSAs with certain characteristics would result in the following selection probabilities:

- 33.3% (one out of three) CBSAs will be selected in strata with high number of safety net hospitals and low past exposure to CMS' bundled payment models. Four strata have this selection probability.
- 25% (1 out of 4) CBSAs will be selected in strata with either high number of safety net hospitals or low past exposure to CMS' bundled payment models (but not both). Eight strata have this selection probability.
- 20% (1 out of 5) CBSAs will be selected in strata with neither high number of safety net hospitals nor low past exposure to CMS' bundled payment models. Four strata have this selection probability.
- 50% (1 out of 2) CBSAs will be selected with the highest number of safety net hospitals (One strata has this selection probability: the 17th stratum).

The 17 selection strata and their relationship to the dimensions discussed above are represented in Table X.A.–03.

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TABLE X.A.-03: SELECTION STRATA AND THEIR PROPOSED SELECTION PERCENTAGES

Selection Strata	Number of safety net hospitals in the CBSA	CBSA's past exposure to CMS' bundled payment models	Average Spend for a Broad Range of Episode Categories in the CBSA	Number of Hospitals within the CBSA	Selection Percentage for CBSAs in strata
1	Low	Low	Low	Low	1/4
2	Low	Low	Low	High	1/4
3	Low	Low	High	Low	1/4
4	Low	Low	High	High	1/4
5	Low	High	Low	Low	1/5
6	Low	High	Low	High	1/5
7	Low	High	High	Low	1/5
8	Low	High	High	High	1/5
9	High	Low	Low	Low	1/3
10	High	Low	Low	High	1/3
11	High	Low	High	Low	1/3
12	High	Low	High	High	1/3
13	High	High	Low	Low	1/4
14	High	High	Low	High	1/4
15	High	High	High	Low	1/4
16	High	High	High	High	1/4
17	Very High	High	High	High	1/2

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Through this selection scheme, CMS would select approximately a quarter of eligible CBSAs listed in Table X.A.–03 across the CBSAs in which TEAM would be implemented. A hospital's probability of being required to participate in TEAM would depend on the stratum their CBSA is in, and would range from 20% to 50%.

We conducted power analyses to identify detectable changes in episode spending between a potential group of CBSAs selected for the model and a potential control group of CBSAs using a Type I error of 0.05 and Type 2 error of 0.2 (implying a power of 0.8). The analysis shows that, if a quarter of eligible CBSAs are selected for TEAM, we will be able to detect 1.5% changes in episode spending, all else being equal. This change in episode spending is within the savings range that CMS might expect to achieve given estimates for surgical episodes from previous episode-based payment models, including BPCI Model 2, CJR, and BPCI Advanced. This is critical to ensuring that CMS is able to assess the model's impact on Medicare spending.

We seek comment on our proposed approach to selecting TEAM participants at § 512.515.

b. Proposed Episodes

(1) Background

A key model design feature for episode-based payment models is the definition of the episodes included in the model. The episode definition has two significant dimensions—(1) a clinical dimension that describes which clinical conditions and associated services are included in the episode; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode.

(2) Overview of Proposed Episodes

In selecting episodes to test in TEAM, we considered a variety of factors, including the number and type of episodes best suited to meet the goals of the model. We chose to limit episode categories for TEAM to those that were included in BPCI Advanced through a robust selection process similar to that used for the CJR model (80 FR 73277). These episode categories represent high-expenditure, high-volume care delivered to Medicare beneficiaries and are evaluable in an episode-based payment model. BPCI Advanced clinical episodes include both surgical episodes, which are triggered by a surgical procedure, and medical episodes that are primarily non-surgical in nature.

While we continue to strive for our models to reduce Medicare expenditures and improve quality of care, we also want to ensure that there is a potential for participating hospitals to succeed. We want the conditions captured by episode categories in TEAM to be clinically similar enough that participants could drive care improvements by streamlining care pathways and transitions between clinical settings. In general, elective surgical procedures are associated with greater clinical homogeneity than unplanned hospitalizations or medical conditions. In addition, when episodes are clinically similar, episode spending is more predictable. Unsurprisingly, medical episodes are associated with greater spending variability. Medical episodes may also be more difficult to manage for hospitals without previous experience implementing value-based care and care redesign activities.

Notably, evaluations of CJR and BPCI Advanced suggest that surgical episode categories do not capture underserved populations to the same degree as medical episodes and that medical episodes may offer relatively greater opportunity to address health equity. Specifically, medical episodes generally have a higher proportion of dual-eligible beneficiaries when compared to surgical episodes. TEAM will test novel ways to improve representation of underserved populations in surgical episodes through targeted flexibilities for safety net hospitals and more broadly defined beneficiary-level social risk adjustment described in section X.A.3.f. of the preamble of this proposed rule). Although we are not proposing medical episodes for TEAM at this time due to their relatively greater clinical heterogeneity, we will consider adding medical episodes in future years of the model. We are soliciting comments on including medical episodes in TEAM, as well as input on which specific medical episodes would best support the goals of the model.

We also selected episodes for this proposed model with a greater proportion of spending in the post-acute period relative to the anchor hospitalization or procedure as such episodes may reflect a greater opportunity to improve care transitions for beneficiaries and reduce unnecessary hospitalizations and emergency care.

Finally, we acknowledge that testing all of the BPCI Advanced episodes in a novel mandatory model could overwhelm participants, as previous mandatory models have only tested a single episode category.

For the reasons discussed previously, we propose testing five surgical episodes in the model—Coronary Artery Bypass Grafting (CABG), Lower Extremity Joint Replacement (LEJR), Surgical Hip and Femur Fracture Treatment (SHFFT), Spinal Fusion, and Major Bowel Procedure. Based on our experience with the BPCI Advanced and CJR models and the stakeholder feedback received in response to the July 2023 Episode-Based Payment Model Request for Information, we believe that beginning the model with these five episode categories is the most reasonable course for TEAM.[591] Specifically, we are proposing to test surgical episodes because they are time-limited with well-defined triggers, have clinically similar patient populations with common care pathways, and have sufficient spending or quality variability, particularly in the post-acute period, to offer participants the opportunity for improvement.

The proposed episodes have been previously tested in BPCI Advanced voluntarily, allowing CMS to assess engagement and gather data. The proposed episodes represent the highest volume and highest cost surgical episodes performed in the inpatient setting. Although CABG and SHFFT episodes were finalized in the Advancing Care Coordination through Episode Payment Models (Cardiac and Orthopedic Bundled Payment Models) Final Rule (CMS–5519–F) on December 20, 2016, that mandatory test was not implemented. The proposed TEAM is the next logical step for applying lessons learned from BPCI Advanced in a mandatory model. TEAM would enable CMS to capture a more diverse population of providers, and potentially beneficiaries.

The proposed Lower Extremity Joint Replacement (LEJR) episode category would include hip, knee, and ankle replacements performed in either the hospital inpatient or outpatient setting. This episode category was selected because, using 2021 data, it was the highest volume, highest cost BPCI Advanced surgical episode category. There were 204,160 episodes with a total cost of $5.01 billion, with more than 40% of spending occurring in the post-acute period.

The proposed SHFFT episode category, referred to as Hip and Femur Procedures except Major Joint in BPCI Advanced, would include beneficiaries who receive a hip fixation procedure in the presence of a hip fracture. It would not include fractures treated with a joint replacement. This episode was selected because it was the second highest volume, and second-highest cost BPCI Advanced surgical episode performed in the inpatient setting, using 2021 data. There were 69,076 episodes with a total cost of $3.22 billion, with more than 63% of spending occurring in the post-acute period.

The proposed CABG episode category would include beneficiaries undergoing coronary revascularization by CABG.[592] This episode was selected because we wanted to maintain the engagement of cardiac surgeons who have participated in prior episode-based models. Among cardiac procedures it was the second highest cost and second highest volume BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. There were 26,259 episodes with a total cost of $1.39 billion; approximately 22% of spending occurred in the post-acute period. We also considered percutaneous coronary intervention (PCI) for TEAM because it was the highest volume and highest cost surgical cardiac episode. However, we did not select this episode because PCI has been described as a low-value service by the Medicare Payment Advisory Commission when performed for stable coronary artery disease,[593] and the majority of PCIs are performed in the outpatient setting and are not associated with an acute event.

The proposed Spinal Fusion episode category would include beneficiaries who undergo certain spinal fusion procedures in either a hospital inpatient or outpatient setting. This episode was selected because it was the third-highest cost BPCI Advanced surgical episode performed in the inpatient setting using

[591] Request for Information; Episode-Based Payment Model.

[592] *https://www.cms.gov/icd10m/version38-fullcode-cms/fullcode_cms/P0008.html.*

[593] MedPAC March 2021 Report to the Congress. *https://www.medpac.gov/.*

2021 data. There were 62,345 episodes with a total cost of $3.2 billion; more than 27% of spending occurred in the post-acute period.

The proposed Major Bowel Procedure episode would include beneficiaries who undergo a major small or large bowel surgery.[594] This episode was selected because it was the fifth-highest volume and fourth-highest cost BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. There were 54,848 episodes with a total cost of $1.95 billion; 37% of spending occurred in the post-acute period.

Each of the episodes provides different opportunities in TEAM to improve the coordination and quality of care, as well as efficiency of care during the episode, based on varying current patterns of utilization and Medicare spending. While these episode categories have been tested previously, we believe TEAM will provide additional information that can be used for potential expansion through its greater focus on care transitions back to primary care, health equity, and refined payment methodology, as described elsewhere in this proposed rule.

In addition, the mandatory nature of TEAM would address selection bias, where high performing hospitals have elected to voluntarily participate in a model but then withdrew from the model in the face of financial losses or uncertainty of receiving financial rewards. In BPCI Advanced, participants were able to select clinical episode categories and, later, service lines, which further ensures selection bias.

We performed an analysis of Medicare FFS claims data, beginning in CY 2021, to estimate the average annual number of historical episodes that extended 30 days post-hospital discharge, and, therefore, would have been included in TEAM. Based on that analysis, we anticipate the number of episodes that TEAM would capture to be approximately 28,088 for CABG; 75,254 for SHFFT; 59,983 for Major Bowel Procedure; 215,957 for LEJR; and 65,968 for Spinal Fusion. The average episode cost for these historical episodes was approximately $48,905 for CABG, $35,501 for SHFFT, $29,184 for Major Bowel Procedure, $21,063 for LEJR, and $46,326 for Spinal Fusion.

As previously stated, we are proposing five episode categories for TEAM to ease TEAM participants into episode accountability. We also intend to add additional episode categories in future performance years of the model, offering a gradual transition to greater episode accountability, and ultimately capturing a larger proportion of FFS spending in value-based care. We would use future notice and comment rulemaking to add episode categories in future performance years.

We seek comment on the five proposed episode categories, described at § 512.525(d) and any additional episode categories we should consider for the model.

(3) Clinical Dimensions of Episodes

We believe that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in this payment model is important for the care redesign that is required for model success. Some of the inpatient procedures that group to the included MS–DRGs are also performed in the outpatient setting. To identify outpatient episodes for TEAM, we propose to use methods similar to BPCI Advanced and CJR. Specifically, we propose to match a hospital's institutional claim for TEAM procedure codes billed through the OPPS.

Therefore, as in the BPCI Advanced and CJR models, hospitals participating in the proposed TEAM would be able to identify beneficiaries in included episodes through their Medicare Severity–Diagnosis Related Group (MS–DRG) during the anchor hospitalization or, for hospital outpatient procedures, by their Healthcare Common Procedure Coding System (HCPCS) codes, allowing active coordination of beneficiary care during and after the procedure.

The MS–DRG for inpatient procedures would determine the ultimate MS–DRG assignment for the hospitalization, unless additional surgeries higher in the MS–DRG hierarchy also are reported.[595] This approach offers operational simplicity for providers and CMS and is consistent with the approach taken by the BPCI Advanced and CJR models to identify beneficiaries whose care is included in those episodes.

We seek comment on our proposal to identify episodes with MS–DRGs and HCPCS for inclusion in TEAM.

(4) Episode Category Definitions

Episode definitions have two significant dimensions—(1) a clinical dimension that describes which clinical conditions and associated services are included in the episode category; and (2) a time dimension that describes the beginning and end of the episode, its length, and when the episode may be cancelled prior to the end of the episode.

For the purposes of TEAM, we propose to define episodes as including all Medicare Part A and Part B items and services described in § 512.525(e), with some exceptions described below and at § 512.525(f), beginning with an admission to an acute care hospital stay (hereinafter ''the anchor hospitalization'') or an outpatient procedure at a hospital outpatient department (HOPD) (hereinafter ''anchor procedure''), and ending 30 days following hospital discharge or anchor procedure.

As previously discussed in section X.A.3.b.(2) of the preamble of this proposed rule, the proposed episode categories were previously tested in BPCI Advanced and were voluntarily selected by BPCI Advanced participants. They represent the highest volume and highest cost surgical episode categories performed in the inpatient setting. We believe, based on current patterns of utilization and Medicare spending, there are still efficiencies to be gained by streamlining care pathways and transitions between clinical settings.

We selected these episode categories because elective surgical procedures are more clinically similar and have greater spending predictability. In addition, these episode categories have a significant proportion of spending in the post-acute period, reflecting a greater opportunity to improve care transitions for beneficiaries and reduce unnecessary hospitalizations and emergency care.

(a) Lower Extremity Joint Replacement Episode Category

As mentioned previously in this section of the proposed rule, we have identified the LEJR episode category for inclusion in this model. This proposed episode category would include hip, knee, and ankle replacements, but exclude arthroplasty of the small joints in the foot. The proposed LEJR episode category would include both hospital inpatient and outpatient procedures reimbursed through the Inpatient Prospective Payment System (IPPS) under select Medicare Severity-Diagnosis Related Groups (MS–DRG) and HOPD procedures billed under select HCPCS codes through the Outpatient Prospective Payment System (OPPS).[596]

[594] *https://www.cms.gov/icd10m/version38-fullcode-cms/fullcode_cms/P0009.html.*

[595] Medical Severity Diagnosis Related Groups (MS–DRGs): Definitions Manual. Version 33.0A. 3M Health Information Systems. (October 1, 2015). *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.*

[596] ICD–10–CM/PCS MS–DRG v38.0 Definitions Manual: *https://www.cms.gov/icd10m/version38-fullcode-cms/fullcode_cms/P0011.html.*

We recognize LEJR has been tested in other episode-based payment models. Given the promising findings for this episode category in those model tests, we believe there is value in continuing to test this episode category under an alternate payment methodology, particularly given the high volume of such procedures among the Medicare population. In addition, as previously mentioned, TEAM would potentially capture underserved populations who were disproportionately underrepresented in CJR. Therefore, we propose to define the LEJR episode category as a hip, knee, or ankle replacement that is paid through the IPPS under MS–DRG 469, 470, 521, or 522 or through the OPPS under HCPCS code 27447, 27130, or 27702. This approach offers operational simplicity for providers and CMS and is consistent with the approach taken by previous models to identify beneficiaries whose care is included in the LEJR episode category.

We note that Medicare-covered outpatient total ankle arthroplasty (TAA) was excluded from both BPCI Advanced and CJR models. However, since its removal from the Inpatient-Only List in 2021, the majority of TAA procedures have shifted to the outpatient setting. For example, in 2022, there were approximately 2,600 outpatient TAAs and only 600 TAAs performed in the inpatient setting. For this reason, and to be consistent with other episodes in the LEJR episode category, we propose that both inpatient and outpatient TAAs would trigger an episode in TEAM.

Based on an analysis of 2021 Medicare FFS claims data for historical LEJR episodes and an estimated number of additional outpatient TAAs, the annual number of potentially eligible beneficiary discharges for this mandatory model nationally would be approximately 226,000. We seek public comment on our proposed definition of LEJR episodes for TEAM at § 512.525(d)(1). We also seek comment on the proposed MS–DRG and HCPCS codes and our proposal to include outpatient TAA in the LEJR episode category.

(b) Surgical Hip & Femur Fracture Treatment (Excluding Lower Extremity Joint Replacement) Episode Category

We propose to define the Surgical Hip and Femur Fracture Treatment (SHFFT) episode as a hip fixation procedure, with or without fracture reduction, but excluding joint replacement, that is paid through the IPPS under MS–DRG 480–482. The SHFFT episode would include beneficiaries treated surgically for hip and femur fractures, other than hip arthroplasty. SHFFT procedures include open and closed surgical hip fixation, with or without reduction of the fracture. The SHFFT episode was selected because it was the second highest volume, and second-highest cost BPCI Advanced surgical episode performed in the inpatient setting, based on an analysis of 2021 Medicare FFS claims data. There were 69,076 episodes with a total cost of $3.22 billion. In addition, more than 63% of spending occurring in the post-acute period, signifying potential opportunity for care improvement. Using that same data for historical SHFFT episodes, the annual number of potentially eligible beneficiary discharges for this episode category nationally would be approximately 85,000.

Together, the LEJR and SHFFT episode categories cover all surgical treatment options for Medicare beneficiaries with hip fracture (that is, hip arthroplasty and fixation). Although a small number of SHFFT procedures are furnished in the outpatient hospital setting, TEAM would only include inpatient procedures, which conforms with hip and femur procedure except major joint episodes under BPCI Advanced.

Thus, we propose to include episodes for beneficiaries admitted and discharged from an anchor hospitalization paid under a SHFFT MS–DRG (480–482) under the IPPS in TEAM. We seek comment on our proposed definition of SHFFT and our proposal to include the SHFFT episode category at § 512.525(d)(2).

(c) Coronary Artery Bypass Graft Episode Category

The proposed CABG episode category would include beneficiaries undergoing coronary revascularization by CABG.[597] This episode category was selected in order to maintain the engagement of cardiac surgeons who have participated in prior episode-based models. Among cardiac procedures, it was the second highest cost and second highest volume BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. There were 26,259 episodes with a total cost of $1.39 billion.

We also considered the percutaneous coronary intervention (PCI) episode category for TEAM because it was the highest volume and highest cost surgical cardiac episode. However, we did not select this episode because PCI has been described as a low-value service by the Medicare Payment Advisory Commission when performed for stable coronary artery disease,[598] and the majority of PCIs are not associated with an acute care hospitalization.

We propose to define the Coronary Artery Bypass Graft (CABG) episode category as any coronary revascularization procedure that is paid through the IPPS under MS–DRG 231–236, including both elective CABG and CABG procedures performed during initial acute myocardial infarction treatment (AMI). Based on an analysis of 2021 Medicare FFS claims data for historical CABG episodes, the annual number of potentially eligible beneficiary discharges for CABG episodes in TEAM would be approximately 30,000. We seek comment on our proposed definition of the CABG episode category and our proposal to include emergent CABG in episodes at § 512.525(d)(3).

(d) Spinal Fusion Category

We propose to include in TEAM the Spinal Fusion episode category for beneficiaries undergoing inpatient and outpatient spinal fusion. The spinal fusion episode category was selected because it was the third-highest cost BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. There were 62,345 episodes with a total cost of $3.2 billion. Based on the high number of episodes and its voluntary selection by participants in BPCI Advanced, we believe there are additional opportunities to improve care for beneficiaries undergoing these procedures.

We propose to define the spinal fusion episode category as any cervical, thoracic, or lumbar spinal fusion procedure paid through the IPPS under MS–DRG 453–455, 459–460, or 471–473, or through the OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633. Based on an analysis of 2021 Medicare FFS claims data and an estimated number of additional outpatient episodes, the annual number of potentially eligible TEAM Spinal Fusion episodes would be approximately 94,000. We seek comment on our definition and inclusion of the Spinal Fusion episode category at § 512.525(d)(4).

(e) Major Bowel Procedure Episode Category

We propose to include in TEAM the Major Bowel Procedure episode category for beneficiaries undergoing inpatient major small bowel and large bowel procedures. This episode

[597] *https://www.cms.gov/icd10m/version38-fullcode-cms/fullcode_cms/P0008.html.*

[598] MedPAC March 2021 Report to the Congress. *https://www.medpac.gov/.*

category was selected because it was the fifth-highest volume and fourth-highest cost BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. There were 54,848 episodes with a total cost of $1.95 billion. We believe there are still opportunities to streamline care pathways and improve care transitions for beneficiaries receiving this care.

We proposed to define the Major Bowel Procedure episode category as any small or large bowel procedure paid through the IPPS under MS–DRG 329–331. Based on an analysis of 2021 Medicare FFS claims data for historical Major Bowel Procedure episodes, the annual number of potentially eligible beneficiary discharges for episodes in TEAM would be approximately 64,000. We seek comment on our proposed definition and inclusion of the Major Bowel Procedure episode at § 512.525(d)(5).

The following Table X.A.-04 summarizes the five proposed episodes and corresponding billing codes that would be used to identify episodes.

TABLE X.A.-04: PROPOSED EPISODE CATEGORIES AND BILLING CODES

Episode Category	Billing Codes (MS-DRG/HCPCS)
LEJR	MS-DRG 469, 470, 521, 522 HCPCS 27447, 27130, 27702
SHFFT	MS-DRG 480, 481, 482
CABG	MS-DRG 231, 232, 233, 234, 235, 236
Spinal fusion	MS-DRG 453, 454, 455, 459, 460, 471, 472, 473 HCPCS 22551, 22554, 22612, 22630, 22633
Major bowel procedure	MS-DRG 329, 330, 331

(5) Items and Services Included in Episodes

Like previous episode-based payment models, TEAM would incentivize comprehensive, coordinated, patient-centered care through inclusive episodes. We propose to include in the episode all items and services paid under Medicare Part A and Part B during the performance period, unless such items and services fall under a proposed exclusion described in section X.A.3.b.(5)(a) of the preamble of this proposed rule.

We propose to include all Part A services furnished during the proposed 30-day post-discharge period of the episode, other than certain excluded hospital readmissions, as post-hospital discharge Part A services are typically intended to be comprehensive in nature. In particular, we believe that claims for services with diagnosis codes that are directly related to the proposed episode categories or the quality and safety of care furnished during the episode, based on clinical judgment (for example, surgical wound infection) and taking into consideration coding guidelines, should be included in an episode. Thus, we propose that items and services for episodes would include the following items and services paid under Medicare Part A and Part B, subject to the proposed exclusions in section X.A.3.b.(5)(a) of the preamble of this proposed rule:

- Physicians' services.
- Inpatient hospital services, including services paid through IPPS operating and capital payments.
- Inpatient psychiatric facility (IPF) services.
- Long-Term Care Hospital (LTCH) services.
- Inpatient Rehabilitation Facility (IRF) services.
- Skilled Nursing Facility (SNF) services.
- Home Health Agency (HHA) services.
- Hospital outpatient services.
- Outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment.
- Part B drugs and biologicals except for those excluded under § 512.525 (f) as proposed.
- Hospice services.
- Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode category is not detected as part of the hospitalization because the procedure was performed by the TEAM participant on an outpatient basis but the patient was subsequently admitted as an inpatient.

We seek comment on the items and services we are proposing to include in TEAM in proposed § 512.525(e).

(a) Items and Services Excluded From Episodes

We propose to exclude from episodes certain Part A and B items and services that are clinically unrelated to the anchor hospitalization or anchor procedure. The proposed exclusions would be applicable to episodes included during the baseline period, the three-year historical period used to construct target prices, as described in section X.A.3.d.(3) of the preamble of this proposed rule, and episodes initiated during a performance year. The proposed exclusions are similar to those excluded from BPCI Advanced, as discussed in detail later in this section.[599] We have used similar exclusions in CMS Innovation Center Models, with minor adjustments, since BPCI and intend to continue to apply them to TEAM. These exclusion lists were developed through a collaborative effort between CMS and external stakeholders and have been vetted broadly in the health care community. We propose to use the BPCI Advanced exclusions list in TEAM based on several years of experience with them and their suitability for episodes in TEAM. The rationale for these exclusions described below is consistent with the rationale for exclusions in the CJR model (80 FR 73304) and in BPCI Advanced.

We propose to exclude from episodes all Part A and B items and services, for both the baseline period and performance years, for hospital admissions and readmissions for specific categories of diagnoses, such as oncology, trauma medical admissions, organ transplant, and ventricular shunts determined by MS–DRGs, as well as all of the following excluded Major Diagnostic Categories (MDC):[600]

[599] A complete list of excluded items, services, and readmission MS–DRGs can be found in the ''BPCI Advanced Exclusions List—MY7 (XLS)'' available under Participant Resources at the CMS BPCI Advanced website.

[600] MDCs are formed by dividing all possible principal diagnoses (from ICD–10–CM) into 25 mutually exclusive diagnosis areas. The diagnoses

- MDC 02 (Diseases and Disorders of the Eye).
- MDC 14 (Pregnancy, Childbirth, and Puerperium).
- MDC 15 (Newborns).
- MDC 25 (Human Immunodeficiency Virus).

We propose to exclude from episodes IPPS new technology add-on payments for drugs, technologies, and services identified by value code 77 on IPPS hospital claims for episodes in the baseline period and performance years.[601] New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid under the MS–DRG system. We believe it would not be appropriate for TEAM to potentially diminish beneficiaries' access to new technologies or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward TEAM participants' actual episode spending. Additionally, new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions. Exclusion of new technology add-on payments for drugs, technologies, or services approved for add-on payments from episodes in TEAM is similar to episode exclusions in the CJR model (80 FR 73303 and73304 and 73315).

We also propose to exclude from episodes OPPS transitional pass-through payments for medical devices as identified through OPPS status indicator H for episodes in the baseline period and performance years. Through the established OPPS review process, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for Medicare beneficiaries. This proposal also is consistent with the BPCI Advanced and CJR model final exclusions policy (80 FR 73308 and 73315).

We propose to exclude from episodes drugs or biologics that are paid outside of the MS–DRG, specifically hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims for episodes in the baseline period and performance years. Hemophilia clotting factors, in contrast to other drugs and biologics that are administered during an inpatient hospitalization and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care for certain beneficiaries. Because we do not believe that there are any spending efficiencies to be gained by including hemophilia clotting factors, we propose to exclude these high-cost drugs from episodes initiated during the baseline period and performance year.

We propose to exclude from episodes certain Part B payments for high-cost drugs and biologicals, low-volume drugs,[602] and blood clotting factors for hemophilia patients billed on outpatient, carrier, and durable medical equipment claims for episodes in the baseline period and initiated in the performance years. These high-cost items are essential to appropriate care of certain beneficiaries and we do not believe including them in the episode would improve any spending or quality of care efficiencies. Specifically, this proposed list would include:

- For episodes included during the baseline period:

++ Drug/biological HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in TEAM during the baseline period;

++ Drug/biological HCPCS codes that are billed in at least 31 episodes in the baseline period, and have a mean allowed cost of greater than $25,000 per episode in the baseline period; and

++ HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file[603] for certain Medicare Part B drugs and biologicals as HCPCS codes with clotting factor = 1, HCPCS codes for new hemophilia clotting factors not in the baseline period, and other HCPCS codes identified as hemophilia.

- For episodes initiated during a performance year, in addition to those listed in the previous bullet, Part B payments for high-cost drugs and biologicals, low-volume drugs, and blood clotting factors for hemophilia billed on outpatient, carrier, and durable medical equipment (DME) claims, including, but not limited to:

++ Drug/biological HCPCS codes that were not included in the baseline period, and appear in 10 or fewer episodes in the performance year;

++ Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of greater than $25,000 per episode in the performance year; and

++ Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of $25,000 or less per episode in the performance year, and correspond to a drug/biological that appears in the baseline period list but was assigned a new HCPCS code between the baseline period and performance year.

++ HCPCS codes for new hemophilia clotting factors not in the baseline period.

Complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded HCPCS codes for Part B services furnished during TEAM episodes after TEAM beneficiary discharge from an anchor hospitalization would be posted on the CMS TEAM website at *https://innovation.cms.gov/initiatives/TEAM.* The lists would apply to all performance years of the model until and unless the lists are updated. We propose that revisions to the exclusion lists would be initiated through rulemaking to allow for public input. Potential updates to the lists could include additions to or deletions from the list, reflect changes to ICD–10–CM coding and the MS–DRGs under the IPPS, or address any other issues that are brought to our attention throughout the course of the TEAM performance period.

We seek comment on the proposed excluded services, the lists of excluded services, and the process for updating the lists of excluded services for TEAM included in § 512.525(f), § 512.525(g), and § 512.525(h).

(b) Beneficiary Inclusion Criteria

We propose to begin an episode with an anchor hospitalization or anchor procedure because of the challenges related to clinical variability leading up to the episodes and identifying unrelated services, given the multiple chronic conditions experienced by many TEAM beneficiaries. We propose that all services that are included in the IPPS (for example, 3-day payment window payment policies) would be included in the episodes. We further propose that the population of Medicare beneficiaries whose care would be included in TEAM would be those beneficiaries who meet all of the following criteria at the time of admission to the anchor hospitalization or anchor procedure:

in each MDC correspond to a single organ system or etiology and in general are associated with a particular medical specialty.

[601] This exclusion is applied during the payment standardization process.

[602] To determine if a drug HCPCS meets the cost or volume thresholds for exclusion, the episodes are pooled across all episode categories.

[603] *https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files.*

- Enrolled in Medicare Part A and Part B.
- Not eligible for Medicare on the basis of end-stage renal disease.
- Not enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- Not covered under a United Mine Workers of America health plan, which provides health care benefits for retired mine workers.
- Have Medicare as their primary payer.

We seek comment on the proposed beneficiary inclusion criteria included in § 512.535.

(c) Initiating Episodes

We propose that, if the beneficiary meets the beneficiary inclusion criteria, an episode would begin when a beneficiary is admitted for an anchor hospitalization or anchor procedure for one of the following MS–DRGs, or by the presence of one of the following HCPCS codes on an outpatient claim (specifically, a hospital's institutional claim for an included outpatient procedure billed through the OPPS):

LEJR MS–DRGs and HCPCS—

- 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities (MCC)).
- 470 (Major joint replacement or reattachment of lower extremity without MCC).
- 521 (Hip replacement with principal diagnosis of hip fracture with MCC).
- 522 (Hip replacement with principal diagnosis of hip fracture without MCC).
- 27447 (Total knee arthroplasty).
- 27130 (Total hip arthroplasty).
- 27702 (Total ankle arthroplasty).

SHFFT MS–DRGs—

- 480 (Hip and femur procedures except major joint with MCC).
- 481 (Hip and femur procedures except major joint with complication or comorbidity (CC)).).
- 482 (Hip and femur procedures except major joint without CC/MCC).

CABG MS–DRGs—

- 231 (Coronary bypass with percutaneous transluminal coronary angioplasty (PTCA) with MCC).
- 232 (Coronary bypass with PTCA without MCC).
- 233 (Coronary bypass with cardiac catheterization with MCC).
- 234 (Coronary bypass with cardiac catheterization without MCC).
- 235 (Coronary bypass without cardiac catheterization with MCC).
- 236 (Coronary bypass without cardiac catheterization without MCC).

Spinal fusion MS–DRGs and HCPCS—

- 453 (Combined anterior/posterior spinal fusion with MCC).
- 454 (Combined anterior/posterior spinal fusion with CC).
- 455 (Combined anterior/posterior spinal fusion without CC/MCC).
- 459 (Spinal fusion except cervical with MCC).
- 460 (Spinal fusion except cervical without MCC).
- 471 (Cervical spinal fusion with MCC).
- 472 (Cervical spinal fusion with CC).
- 473 (Cervical spinal fusion without CC/MCC).
- 22551 (Anterior cervical spinal fusion with decompression below C2).
- 22554 (Anterior cervical spinal fusion without decompression).
- 22612 (Posterior or posterolateral lumbar spinal fusion).
- 22630 (Posterior lumbar interbody lumbar spinal fusion).
- 22633 (Combined posterior or posterolateral lumbar and posterior lumbar interbody spinal fusion).

Major small and large bowel procedure MS–DRGs—

- 329 (Major small and large bowel procedures with MCC).
- 330 (Major small and large bowel procedures with CC).
- 331 (Major small and large bowel procedures without CC/MCC).

We propose that the episode start date will be the day of the anchor procedure for outpatient procedures or the date of admission on the IPPS claim associated with the anchor hospitalization that triggered the episode. However, if an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient procedure for the same episode category, we propose to begin the episode on the date of the outpatient procedure rather than the date of the inpatient admission.

We recognize there could potentially be episodes initiated in TEAM as a result from a TEAM beneficiary being transferred from one hospital to another, where at least one or both hospitals are TEAM participants and where at least one of the hospital admissions are for a MS–DRG that would initiate an anchor hospitalization in TEAM. In the BPCI Advanced model, this is viewed as one continuous hospitalization, whereas in the CJR model and in the proposed TEAM, it is viewed as two separate hospitalizations that may result in an episode initiating depending on the hospital participation in the model and the MS–DRGs involved in the hospital admissions. Specifically, if the initial inpatient admission is at a TEAM participant for a proposed MS–DRG in TEAM, then it would initiate an anchor hospitalization and the resulting transfer to the second hospital would not initiate a new anchor hospitalization, rather it would be included in the episode initiated from the first hospitalization. However, if the initial inpatient admission is for an MS–DRG not proposed in TEAM, then an anchor hospitalization is not initiated and the resulting transfer to the second hospital could initiate an episode depending on the second hospitals participation status and the MS–DRG for the inpatient admission.

We considered mimicking the BPCI Advanced model and proposing a transfer policy where a TEAM beneficiary that is transferred from one hospital to another would be considered one continuous hospitalization. Specifically, we considered defining an acute-to-acute hospital transfer as consecutive inpatient stays for a TEAM beneficiary where the admission date of the latter inpatient hospital stay is the same as the discharge date of the initial hospital inpatient stay for different acute care hospitals. This would mean that acute-to-acute hospital transfers are treated as one continuous hospitalization and would be assigned the admission date and the hospital from the first leg of the transfer and the MS–DRG and discharge date from the last leg of the transfer. For example, hospital A is a TEAM participant and hospital B is not a TEAM participant. A beneficiary is admitted to hospital A on January 1st for an MS–DRG 637 (diabetes) not in TEAM and discharged on January 5th with a transfer to hospital B on the same day. The beneficiary is admitted to hospital B for MS–DRG 470 (LEJR) and is discharged on January 10th. In this example, the episode is attributed to hospital A and is considered a LEJR episode with an anchor hospitalization start date of January 1st and an anchor hospitalization end date of January 10th. All of the spending between both hospitalizations would be captured in the episode. If the example would be reversed, and hospital A was not a TEAM participant and hospital B was a TEAM participant, then neither hospital would be attributed the episode since hospital A is not a participant and the transfer policy prevents the episode from being attributed to hospital B. We recognize this policy helps to keep the initial hospital accountable and may mitigate perverse incentives to transfer a beneficiary, however, it does increase complexity when determining when an episode is initiated, and which hospital

is accountable for the episode. We also note that the BPCI Advanced model included additional requirements in their transfer policy, where if one of the hospitals was a critical access hospital or a PPS-exempt cancer hospital or if one of the inpatient admissions was for a MS–DRG on the exclusions list, the episode was cancelled. We seek comment on whether we should consider a transfer policy similar to BPCI Advanced for TEAM.

We seek comment on our proposal for initiating TEAM episodes based on MS–DRG or HCPCS included in § 512.510.

(d) Episode Length

The proposed episodes would cover time periods marked by significant PAC needs, potential complications of surgery, and short-term, intense management of chronic conditions that may be destabilized by the surgery. We believe that hospitals have substantial ability to influence the quality and efficiency of care that TEAM beneficiaries receive over the weeks and months following a procedure. For this reason, both CJR and BPCI Advanced utilize a 90-day post-discharge episode duration.

An episode duration longer than 30 days poses a greater risk for the hospital because of variability due to medical events outside the intended scope of the model. Our analysis of BPCI Advanced episodes found that the need for care for chronic conditions and other non-anchor MS–DRG-related conditions becomes much more prevalent in days 31 to 90 following hospital discharge. Longer episodes increase the potential for ACO overlap (where a beneficiary aligned or assigned to an ACO has an episode included in TEAM), are associated with a greater number of episode-level exclusions in the post-discharge period and are more likely to include potential readmissions for an unrelated condition. Shorter episode lengths are used in other models that employ total cost-of-care approaches. In the Medicare Spending Per Beneficiary (MSPB) measure of the Hospital Value-Based Program (HVBP), episodes include Part A and Part B payments for services furnished three days prior to a patient's inpatient stay and extend for 30 days after discharge.

We believe reducing episode duration to 30 days could both sustain the spending reductions demonstrated in BPCI Advanced and CJR and mitigate some of the current challenges experienced between ACOs, hospitals, and other providers. A 30-day episode would position the specialist as the principal provider near the anchor event with a hand off back to the primary care provider for longitudinal care management and we believe that ACOs are better equipped to address the population health needs of Medicare beneficiaries.

Additionally, the majority of episode spending occurs in the first 30 days following discharge or the anchor procedure. Based on an internal analysis of BPCI Advanced episodes between 2020 and 2022, seventy-five percent of episode spending occurred in the first 30 days of the episode and 90 percent occurred in the first 60 days. We expect TEAM would continue to provide hospitals with opportunities to improve care and incentivize coordinated, quality care among acute care hospitals, HOPDs, physicians, and PAC providers throughout care transitions, given that the majority of episode spending during 90-day episodes occurred in the first 30 days.

Based on the rationale noted earlier, we propose that episodes end 30 days after discharge from the anchor hospitalization or anchor procedure and that day 1 of the 30-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization. To the extent that a Medicare payment for services included in an episode spans a period of care that extends beyond the episode duration, we propose that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending. The proposal for a 30-day post-discharge episode length is included in § 512.537(a)(1). We seek comment on our proposal to implement a 30-day post-discharge episode length. We also seek comment on alternative episode durations, such as a 60-day or 90-day post-discharge episode length.

(e) Cancelling Episodes

Similar to the CJR model, we propose that once an episode begins, the episode continues until the end of the episode as described in the following section, unless the episode is cancelled because the beneficiary ceases to meet any of the general beneficiary inclusion criteria described in section X.A.3.b.(5)(b) of the preamble of this proposed rule.

We believe it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion because the episode target price reflects full payment for the episode, yet we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price.

In the case that a beneficiary has a subsequent admission for an episode on the same day as or within 3 days of an outpatient procedure from the same episode category, the outpatient episode would be not initiate an anchor procedure and the outpatient procedure would instead initiate an anchor hospitalization. That is, the anchor hospitalization start date will be that of the outpatient procedure. We propose this policy in order because we believe that an inpatient episode should take precedence over an outpatient procedure performed on the same day, given the likelihood of higher spend associated with the inpatient episode and potential for higher clinical acuity.

We propose to cancel the episode if a beneficiary dies during the anchor hospitalization or anchor procedure, rather than at any point during the post-discharge period of the episode, as is done in BPCI Advanced. As discussed in the CJR Final Rule, we believe there would be limited incentive for efficiency that could be expected when death occurs during the anchor hospitalization itself (80 FR 73318).

As discussed in the EPM proposed rule (81 FR 50841), we consider mortality to be a harmful beneficiary outcome that should be targeted for improvement through care redesign for these clinical conditions. We do not believe that it would be appropriate to exclude beneficiaries from episodes who die any time during the episode. Instead, we propose to maintain beneficiary episodes in TEAM unless death occurs during the anchor hospitalization or anchor procedure. We would calculate actual episode spending when beneficiaries die following discharge from the anchor hospitalization or anchor procedure, but within the 30-day post-hospital discharge episode duration and reconcile it against the target price. We believe this proposal would encourage TEAM participants to actively manage beneficiaries to reduce their risk of death, especially as death would often be preceded by expensive care for emergencies and complications. Therefore, we propose to cancel episodes for death only during the anchor hospitalization or anchor procedure.

Finally, we propose that episodes subject to extreme and uncontrollable circumstances (EUC) would be canceled, meaning that the services associated with the episode would continue to be paid through Medicare FFS but the episode would not be reconciled against a target price. We propose to base the TEAM EUC definition on the definition finalized in

the CJR 2018 Final Rule (83 FR 26604), which was designed to address the extreme and uncontrollable costs associated with natural disasters such as hurricanes, flooding, and wildfires. Specifically, we propose that the EUC policy would apply to TEAM participants located in a county where both: (1) a major disaster has been declared under the Stafford Act; and (2) section 1135 waivers have been issued. We believe that it is appropriate for our EUC policy to apply only in the narrow circumstance of a major disaster, which is catastrophic in nature and tends to have significant impacts on infrastructure, rather than the broader grounds for which an emergency could be declared. In regard to determining the start date of episodes to which the EUC would apply, we stated our belief that a episodes initiated during an emergency period or in the 30 days before the start date of an emergency period (as defined in section 1135(g) of the Act) should reasonably capture those beneficiaries whose high episode costs could be attributed to extreme and uncontrollable circumstances.

In summary, we propose that the following circumstances would cancel an episode:

- The beneficiary no longer meets the criteria for inclusion.
- The beneficiary dies during the anchor hospitalization or anchor procedure.
- The participating hospital is subject to the EUC policy.

When an episode is canceled, we propose that the services furnished to beneficiaries prior to and following the episode cancellation would continue to be paid by Medicare as usual but there would be no episode spending calculation that would be reconciled against the TEAM target price (see section X.A.3.d.(5)(f) of the preamble of this proposed rule). As discussed in section X.A.3.h. of the preamble of this proposed rule, waivers of program rules applicable to beneficiaries in episodes would apply to the care of beneficiaries who are in episodes at the time the waiver is used to bill for a service that is furnished, even if the episode is later canceled.

We seek comment on our proposals to cancel episodes once they have begun but prior to the end of the 30-day post-discharge period included in § 512.537(b).

c. Quality Measures and Reporting

(1) Background

As discussed in the CJR model final rule (80 FR 73358), Medicare payment policy has moved away from FFS payments unlinked to quality of care. Through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs like the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act), the Hospital Value-Based Purchasing (VBP) Program (subsection (o) of section 1886), the Hospital-Acquired Condition (HAC) Reduction Program (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (subsection (p) of section 1886), where payment reflects the quality of care delivered to Medicare beneficiaries. The CJR model similarly incorporates pay-for-performance, offering TEAM participants the potential for financial reward based on quality performance or, in some cases, quality improvement. Through the use of quality measures, CMS is also able to pursue objectives beyond resource alignment, such as the development of new quality measures and performance indicators.[604] Additionally, CMS may incorporate new quality measures, re-evaluate or improve existing quality measures, or adjust a quality measure set to take effect at the start of each Model Year, or at other times specified by CMS.

We believe that episode payment models such as the proposed TEAM should include pay-for performance methodologies that incentivize improvements in patient outcomes while simultaneously lowering health care spending. We also believe that improved quality of care, specifically achieved through coordination and communication among providers, patients, and their caregivers, can favorably influence patient outcomes. We are proposing that TEAM would incorporate quality measures that focus on care coordination, patient safety, and patient reported outcomes (PROs) which we believe represents areas of quality that are particularly important to patients undergoing acute procedures. Finally, wherever possible, we would align TEAM quality measures with those used in ongoing models and programs to minimize participant burden. Our goal is to focus on improving beneficiary quality of care and capture meaningful quality data for use in the TEAM pay-for-performance methodologies.

We are starting with a parsimonious set of quality measures that are being tied to payment and plan to incorporate more PRO–PMs in the future of the model. We recognize that there are some gaps in the proposed measures with respect to post-acute care settings and limited measures for episode-specific PROs. We considered including generic PRO data to support the collection and reporting of PROs, similar to the CJR model requiring voluntary submission of the Veterans RAND 12 Item Health Survey (VR–12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey. However, we recognize PRO collection and reporting may increase participant and patient burden and we do not want to impose this on TEAM participants for generic PRO data since it may be less clinically meaningful to the episodes that would be tested in TEAM. We will continue to assess the evolving inventory of measures and refine measures based on public comments, changes to payment methodologies, recommendations from TEAM participants and their collaborators, and new CMS episode measure development activities.

We are proposing that the proposed TEAM's quality measures would be scored according to the methodology described in section X.A.3.d.(5)(e) of the preamble of this proposed rule to calculate the CQS. The CQS would be combined with the TEAM participants' reconciliation amount, as specified in section X.A.3.d.(5)(g) of the preamble of this proposed rule, during the reconciliation process to tie quality performance to payment.

While we believe the proposed measure set would provide CMS with sufficient measures to monitor quality, and to calculate scoring on quality performance, we may adjust the measure set in future performance years by adding new measures or removing measures, if we determine those adjustments to be appropriate at the time. We note that a selection of these measures may be used for evaluation purposes as well. Prior to adding or removing measures for monitoring quality and calculating scores for quality performance, we would use notice and comment rulemaking.

(2) Selection of Proposed Quality Measures

As proposed, TEAM is designed to provide financial incentives for improving coordination of care for beneficiaries. We expect care redesign activities to reduce post-surgical complications and hospital readmissions and enhance patient experience and outcome. Furthermore, we acknowledge that achieving savings while continuing to ensure high-quality

[604] Damberg CL et al., Research Report: Measuring Success in Health Care Value-Based Purchasing Programs, Summary and Recommendations. RAND (2014). Available from *http://www.rand.org/content/dam/rand/pubs/research_reports/RR300/RR306z1/RAND_RR306z1.pdf.*

care for Medicare FFS beneficiaries will require close collaboration among hospitals, physicians, PAC providers, and other providers. In order to encourage greater care collaboration among the providers of TEAM beneficiaries, we propose three measures as described in section X.A.3.c.(3) of the preamble of this proposed rule. These measures would be used to determine hospital quality of care and eligibility for a TEAM reconciliation payment.

The measures we are proposing are—

- For all TEAM episodes: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356);
- For all TEAM episodes: CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135); and
- For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618).

Beginning in Performance Year 1 and continuing for the duration of the model, we propose to adjust reconciliation amounts by the TEAM participants' CQS based on their performance of quality measures previously listed.

We are initially proposing these three quality measures due to their: (1) Alignment with the goals of TEAM; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including the Hospital IQR and HAC Reduction Programs; and (3) alignment to CMS priorities, including the CMS National Quality Strategy which has goals that support safety, outcomes, and engagement. We believe the three quality measures we propose to link to payment reflect these goals and accurately measure hospitals' level of achievement on such goals.

We note that shared-decision making (SDM) is an important aspect of care around elective procedures, including elective procedures captured in episodes such as the LEJR episode and Spinal Fusion episode. Use of SDM prior to episode initiation can serve as an important tool to ensure appropriate care. SDM allows the clinician and patient to have informed discussion about treatment options, balancing the risks and expected outcomes with a patient's preferences and values, and can help contribute to ensuring appropriate use of procedures and minimization of low value care. CMS has taken steps to incorporate SDM in care pathways, such as requiring SDM interaction prior to ICD implantation for certain patients for national coverage determinations.[605] However, implementing SDM in episode-based payment models such as TEAM poses challenges with respect to the timing of the patient/provider interaction and when an episode is initiated. While there are upstream opportunities for SDM in the case of elective surgical episodes, unplanned or non-elective episodes may be less conducive to SDM. Although we are not proposing a measure initially, we are seeking feedback on the opportunity for TEAM to capture quality data related to SDM between patients and providers, and avoidance of low value care and procedures. We invite public comment on whether such a measure concept or any existing measures would be appropriate for TEAM.

Lastly, we also recognize that there are certain measures on the 2023 Measures Under Consideration (MUC) List[606] [607] that may be more clinically meaningful and specific to the episodes in TEAM. These measures are as follows:

- Hospital Harm—Falls with Injury (MUC2023–048).
- Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (MUC2023–049).
- Hospital Harm—Postoperative Respiratory Failure (MUC2023–050).

These three outcome measures focus on improving quality and health outcomes across a beneficiary's care journey and allow for hospitals to better align and coordinate care across various programs and care settings. TEAM is seeking further comment on these three MUC measures, and potentially replacing the CMS PSI 90 measure beginning in 2027, TEAM's second performance year. This timeline will allow TEAM participants to have one year to gain experience with reporting the measures in the Hospital IQR program before their performance is tied to payment beginning in TEAM's second performance year. Further details on these MUC measures can be found in section X.A.3.c.(3)(d) of the preamble of this proposed rule.

[605] *https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=288.*

[606] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx.*

[607] Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf.*

(3) Proposed Quality Measures

(a) Hybrid Hospital-Wide All-Cause Readmission Measure With Claims and Electronic Health Record Data (CMIT ID #356)

Hospital readmission, for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications. Readmissions are also a major source of patient and family stress and may contribute substantially to loss of functional ability, particularly in older patients. Some readmissions are unavoidable and result from inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care. Transitional care includes effective discharge planning, transfer of information at the time of discharge, patient assessment and education, and coordination of care and monitoring in the post-discharge period. Numerous studies have found an association between quality of inpatient or transitional care and early (typically 30-day) readmission rates for a wide range of conditions.[608] In 2013, CMS contracted with Yale New Haven Services Corporation, Center for Outcomes Research and Evaluation (CORE) to demonstrate whether clinical data derived from electronic health records (EHRs) could be used to reengineer and enhance the Hospital-Wide All-Cause Unplanned Readmission (HWR) measure.[609] Under the contract with CMS, Yale CORE identified a set of core clinical data elements (CCDE) that are feasibly extracted from hospital EHRs and are related to patients' clinical status at the start of an inpatient encounter.

We propose including the Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data (CMIT ID #356) measure in TEAM, for all episode categories. Previously, within the CJR rule, CMS proposed using the Hospital-Level 30-day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) measure because we believed that this measure aligned with CMS priorities to improve the rate of LEJR complications and readmissions, while improving the

[608] Frankl SE, Breeling JL, Goldman L. Preventability of emergent hospital readmission. American Journal of Medicine. Jun 1991;90(6):667–674.

[609] *https://qualitynet.cms.gov/inpatient/measures/hybrid/methodology.*

overall patient experience. As a result of stakeholder feedback voicing concerns over the requirements already set in place by the Hospital Readmissions Reduction Program for this measure, the Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) was not included in the CJR Model. Our rationale for including the Hybrid HWR measure within TEAM is because the increased use of EHRs by hospitals creates an opportunity to incorporate clinical data into outcome measures without the laborious process of extracting them from paper medical records. Although claims-based risk adjustment has been shown to be comparable to risk adjustment using clinical data when observing hospital-level performance, clinical providers continue to express preference for using patient-level clinical data.[610] [611] Additionally, we believe this version of HWR provides an opportunity to align the measure with clinical decision support systems that many providers utilize to alert care teams about patients at increased risk of poor outcomes, such as readmission, in real time during the inpatient stay. Further, utilizing the same variables to calculate hospital performance that are used to support clinical decision, we believe, would be clinically sensible and cost effective, as it may reduce the burden of EHR data mapping and extraction required for quality reporting.

In addition, clinical data captured in electronic health records are recorded by clinicians who are interacting with the patient and who value the accuracy of the data to guide the care they provide. Therefore, many clinical data elements that are captured in real-time to support patient care are less susceptible to gaming, coding drift, and variations in billing practices compared with administrative data used for billing purposes. These reporting processes allow for more stable measurements over time. Finally, the measures that are included within HRRP do not capture some of the episodes that we are proposing for TEAM. The Hybrid HWR measure is one of the only existing readmission measures that captures readmission data for patients following procedures such as spine surgery. By using the Hybrid HWR measure, we are inclusive of the specified episodes and encourage broader efforts to reduce unnecessary returns to the hospital at participating hospitals within TEAM.

For TEAM, we propose to use the measure specifications detailed here: *https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS529v4.html* and *https://qualitynet.cms.gov/inpatient/measures/hybrid/methodology.* If we were to remove the measure, we would use notice and comment rulemaking. This measure would be a pay-for-performance measure beginning in Performance Year 1 and scored in accordance with our proposed methodology in section X.A.3.d.(5)(e) of the preamble of this proposed rule.

We seek public comment on our proposal to include the Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data measure in TEAM at § 512.547(a)(1).

(b) CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135)

The Agency for Healthcare Research and Quality (AHRQ) developed patient safety indicators for health providers to identify potential in hospital patient safety problems for targeted institution-level quality improvement efforts. These Patient Safety Indicators (PSIs) are comprised of 26 measures (including 18 provider-level indicators) that highlight safety-related adverse events occurring in hospitals following operations, procedures, and childbirth. AHRQ developed the PSIs after a comprehensive literature review, analysis of available ICD codes, review by clinical panels, implementation of risk adjustment, and empirical analyses. The CMS Patient Safety and Adverse Events Composite (CMS PSI 90) is used in the HAC Reduction Program to support CMS public reporting and pay-for-performance. The CMS PSI 90 measure is calibrated using the Medicare fee-for-service population and based on the AHRQ Patient Safety Indicators. The CMS PSI 90 measure summarizes patient safety across multiple indicators, monitors performance over time, and facilitates comparative reporting and quality improvement at the hospital level. The CMS PSI 90 composite measure intends to reflect the safety climate of a hospital by providing a marker of patient safety during the delivery of care. However, we are aware of the common stakeholder concerns surrounding the CMS PSI 90 measure, including the following: [612]

- PSI 90 may be associated with adverse prioritization for preventing some conditions over others. Not all conditions are equal with respect to prevention guidelines.

++ Sepsis prevention may include use of prophylactic antibiotics.

++ Fall prevention requires assessment of fall risk and appropriately applied remediation methods.

- Pressure injury prevention consists of a time-consuming, complex series of unrelated tasks for nurses, consisting of daily skin checks and risk assessments, repositioning every 3 to 4 hours, and managing moisture and incontinence among other tasks.
- Simple clinical decision points can expose patients to many risks reflected in PSI 90; however, PSI 90 weighting system may influence risk because HACs are weighted in PSI 90 based on volume and harm.
- The PSI 90 composite score could create incentives to prioritize low hanging fruit (for example, procedures and treatments that are directly remunerated) over pressure injury prevention.

We propose including the CMS PSI 90 measure in TEAM, for all episode categories, because it includes a broad array of safety events, many of which are relevant to patients in the episodes, are familiar to hospitals and have no additional burden. CMS would use the CMS PSI 90 software to produce the CMS PSI 90 results. Since CMS is currently using the CMS PSI 90 measure in certain quality programs, including the Hospital-Acquired Condition Reduction Program, we do not anticipate additional administrative burden for TEAM participants.

For TEAM, we propose to use the measure specifications detailed here: *https://qualitynet.cms.gov/inpatient/measures/psi/resources.* If we were to remove the measure, we would use notice and comment rulemaking. This measure would be a pay-for-performance measure beginning in performance year 1 and scored in accordance with our proposed methodology in section X.A.3.d.(5)(e) of the preamble of this proposed rule.

We seek public comment on our proposal to include the CMS PSI 90 measure in TEAM at proposed § 512.547(a)(2) and are also seeking comment on other hospital level safety measures appropriate for these episodes

[610] Keenan PS, Normand SL, Lin Z, Drye EE, Bhat KR, Ross JS, et al. An administrative claims measure suitable for profiling hospital performance on the basis of 30-day all-cause readmission rates among patients with heart failure. Circ Cardiovasc Qual Outcomes. 2008 Sep;1(1):29–37. PubMed PMID: 20031785. Epub 2008/09/01. eng.

[611] Krumholz HM, Lin Z, Drye EE, Desai MM, Han LF, Rapp MT, et al. An administrative claims measure suitable for profiling hospital performance based on 30-day all-cause readmission rates among patients with acute myocardial infarction. Circ Cardiovasc Qual Outcomes. 2011 Mar;4(2):243–52. PubMed PMID: 21406673. PMCID: PMC3350811. Epub 2011/03/17. eng.

[612] Adverse Effects of the Medicare PSI 90 Hospital Penalty System on Revenue-Neutral Hospital-Acquired Conditions (Jun 2020).

that are not already tied to payment in CMS programs. We also invite public comment on the ones that were on the 2023 MUC list and the possible approach to transition from CMS PSI 90 to the three measures beginning in TEAM's second performance year.

(c) Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618)

As part of the CMS Innovation Center's Strategy Refresh, TEAM is working to align with the Center's Patient-Reported Outcome Measure Strategy. This strategy supports the CMS Innovation Center's Advancing Quality Initiative, which aims to support a more person-centered quality strategy in accountable care and specialty care models and demonstrations. The Patient-Reported Outcome Measure Strategy aims to increase the use of patient-reported measures in CMS Innovation Center models and demonstrations. PROs are reported by the patient and capture a person's perception of their own health through surveys and questionnaires. Broadly, patient-reported data includes PROs and ePROs, which is the electronic capture of this data; patient-reported outcome measures (PROMs), which reflect how the PRO data is reported (for example, a survey instrument); and patient-reported outcome-based performance measures (PRO–PMs), which are reliable and valid quality measures of aggregated PRO data reported through a PROM and potentially used for performance assessment.

The CJR model includes voluntary reporting of PRO data. In order to meet the requirements for successful submission of PRO data, hospitals must submit the Veterans RAND 12 Item Health Survey (VR–12) or Patient-Reported Outcomes Measurement Information System (PROMIS) Global-10 generic PRO survey; and the (HOOS Jr.)/(KOOS Jr). or HOOS/KOOS subscales PRO survey for patients undergoing eligible elective primary THA/TKA procedures. The Center for Clinical Standards and Quality (CCSQ) was able to use the CJR THA/TKA PRO data collection to develop the THA/TKA PRO–PM as a part of the Hospital IQR Program, included in the FY 2023 IPPS/LTCH PPS Final rule (87 FR 48780).

Elective THA/TKAs are most commonly performed for degenerative joint disease, or osteoarthritis, which is the most common joint disorder in the US, affecting more than 32.5 million, or 1 in every 7, US adults.[613] [614] This condition is one of the leading causes of disability among non-institutionalized adults; roughly 80% of patients with osteoarthritis have some limitation in mobility.[615] [616] Osteoarthritis also significantly burdens the health care system—in 2017, it was the second most expensive treated condition across all payers in US hospitals, and in 2018, it accounted for approximately 1,128,000 hospitalizations.[617] [618] [619] THAs and TKAs offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without conferring a high risk of complications or death.[620] [621] Over 1 million hip and knee replacements are performed annually in the US, 60% of which are paid for by Medicare. This number is expected to double by 2030 with an estimated annual cost of $50 billion to Medicare.[622]

In order to encourage greater use of patient-reported outcome data, we are proposing to require submission of THA/TKA PRO–PM. However, we recognize that this PRO–PM is only applicable to the LEJR episode category and seek comment on other PROs or PROMs that would be applicable to other episode categories tested and could be incorporated in future performance years of TEAM. Please note, that the addition of the use of generic PROs may be applicable across numerous episodes versus PROs that are more episode specific to given procedures. Also, we recognize that hospitals will be newly adapting to the Hospital IQR Program requirement for the THA/TKA PRO–PM but that infrastructure and process development should make the incorporation of future PRO–PMs less burdensome.

For TEAM, we propose to use the measure specifications detailed here: *https://qualitynet.cms.gov/files/631b6163642a6000163edbf0?filename=THA_TKA-PRO-PM_MeasMthdlgy.pdf.* If we were to remove the measure, we would use notice and comment rulemaking. This measure would be a pay-for-performance measure beginning in performance year 1 and scored in accordance with our proposed methodology in section X.A.3.d.(5)(e) Of the preamble of this proposed rule.

We seek public comment on our proposal to include the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary THA/TKA measure in TEAM at § 512.547(a)(3).

(d) Measures Under Consideration for Future Rulemaking

We recognize there are other measures that may be more clinically relevant to the proposed TEAM clinical episode categories but are not yet being used in the Hospital IQR Program. Therefore, we are seeking comment on requiring submission of the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (MUC2023–049) measure for use in all of our episode categories. This measure assesses the percentage of surgical inpatients who experienced a complication and then died within 30-days from the date of their first ''operating room'' procedure. Failure-to-rescue (FTR) is defined as the probability of death given a postoperative complication.

We believe inclusion of the potential FTR measure in TEAM would allow hospitals to identify opportunities to improve their quality of care. Hospitals and health care providers benefit from knowing not only their institution´s mortality rate, but also their institution´s ability to rescue patients after an adverse occurrence. Using a failure-to-rescue measure is especially important if hospital resources needed for preventing complications are different from those needed for rescue. From a research and policy perspective,

[613] Zhang, Y. and J.M. Jordan, Epidemiology of osteoarthritis. Clin Geriatr Med, 2010. 26(3): p. 355–69.

[614] Centers for Disease Control and Prevention. Osteoarthritis (OA). 2020; Available from: *https://www.cdc.gov/arthritis/basics/osteoarthritis.htm.*

[615] Guccione, A.A., et al., The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. Am J Public Health, 1994. 84(3): p. 351–8.

[616] Michaud, C.M., et al., The burden of disease and injury in the United States 1996. Popul Health Metr, 2006. 4: p. 11.

[617] Levit, K., et al. HCUP Facts and Figures, 2006: Statistics on Hospital-based Care in the United States. 2008; Available from: *https://www.hcupus.ahrq.gov/reports/factsandfigures/facts_figures_2006.jsp.*

[618] Healthcare Cost and Utilization Project. HCUP Fast Stats—Most Common Diagnoses for Inpatient Stays 2021; Available from: *https://www.hcupus.ahrq.gov/faststats/NationalDiagnosesServlet?year1=2018&characteristic1=0&included1=1&year2=2017&characteristic2=0&included2=1&expansionInfoState=hide&dataTablesState=hide&definitionsState=hide&exportState=hide.*

[619] Liang, L., B. Moore, and A. Soni, National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2017. HCUP Statistical Brief #261. 2020.

[620] Lopez, C.D., et al., Hospital and Surgeon Medicare Reimbursement Trends for Total Joint Arthroplasty. Arthroplast Today, 2020. 6(3): p. 437–444.

[621] Rissanen, P., et al., Health and quality of life before and after hip or knee arthroplasty. The Journal of Arthroplasty, 1995. 10(2): p. 169–175.

[622] Lopez, C.D., et al., Hospital and Surgeon Medicare Reimbursement Trends for Total Joint Arthroplasty. Arthroplast Today, 2020. 6(3): p. 437–444.

knowing the failure-to-rescue rate in addition to the mortality rate would improve our understanding of mortality statistics. Since the death rate appears to be composed of two distinct rates, quality of care measurement may be improved if both mortality and FTR rates are reported instead of relying on the adjusted mortality rate alone. Failure to rescue measures have been repeatedly validated by their consistent association with nurse staffing, nursing skill mix, technological resources, rapid response systems, and other activities that improve early identification and prompt intervention when complications arise after surgery.

We are also seeking comment on requiring submission of two hospital harm measures for potential use in TEAM; the Hospital Harm—Falls with Injury (MUC2023–048) and the Hospital Harm—Postoperative Respiratory Failure (MUC2023–050).

We believe including the Hospital Harm—Falls with Injury (MUC2023–048) would address the importance of patient safety in the acute care setting. We recognize that inpatient falls are among the most common incidents reported in hospitals and can increase length of stay and patient costs. Due to the potential for serious harm associated with patient falls, ''patient death or serious injury associated with a fall while being cared for in a health care setting'' is considered a Serious Reportable Event by the National Quality Forum (NQF).

Falls (including unplanned or unintended descents to the floor) can result in patient injury ranging from minor abrasion or bruising to death as a result of injuries sustained from a fall. While major injuries (for example, fractures, closed head injuries, internal bleeding) (Mintz, 2022) have the biggest impact on patient outcomes, 2008–2021 data findings from the 2022 Network of Patient Safety Databases (NPSD) demonstrated that 41.8% of falls resulted in moderate injuries such as skin tear, avulsion, hematoma, significant bruising, dislocations and lacerations requiring suturing. Moderate injury is, as defined by NDNQI, that resulted in suturing, application of steric-strips or skin glue, splinting, or muscle/joint strain (Press Ganey, 2020). NPSD findings also demonstrated that mild to moderate level of harm represent 24.2%, 0.4%—severe harm, and 0.1%—death (levels of harm definitions developed by WHO, 2009).

By focusing on falls with major and moderate injuries, the goal of this hospital harm eCQM is to raise awareness of fall rates and, ultimately, to improve patient safety by preventing falls with injury in all hospital patients. The purpose of measuring the rate of falls with major and moderate injury events is to improve hospitals' practices for monitoring patients at high risk for falls with injury and, in so doing, to reduce the frequency of patient falls with injury.[623] [624] [625] [626]

Additionally, we are considering including the Hospital Harm—Postoperative Respiratory Failure (MUC2023–050). This eCQM assesses the proportion of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure (PRF). PRF is defined as unplanned endotracheal reintubation, prolonged inability to wean from mechanical ventilation, or inadequate oxygenation and/or ventilation, and is the most common serious postoperative pulmonary complication, with an incidence of up to 7.5% (the incidence of any postoperative pulmonary complication ranges from 10–40%).[627] This measure addresses the prevalence of PRF and the incidence variance between hospitals. PRF is a serious complication that can increase the risk of morbidity and mortality, with in-hospital mortality resulting from PRF estimated at 25% to 40%.[628] Surgical procedures complicated by PRF have 3.74 times higher adjusted odds of death than those not complicated by respiratory failure, 1.47 times higher odds of 90-day readmission, and 1.86 times higher odds of an outpatient visit with one of 44 postoperative conditions (for example, bacterial infection, fluid and electrolyte disorder, abdominal hernia) within 90 days of hospital discharge.[629] PRF is additionally associated with prolonged mechanical ventilation and the need for rehabilitation or skilled nursing facility placement upon discharge.[630]

The incidence of PRF varies by hospital, with higher reported rates of PRF in nonteaching hospitals than teaching hospitals (Rahman, et al., 2013). Additionally, one study found that the odds of developing PRF increased by 6% for each level increase in hospital size from small to large.[631] This finding suggests that there remains room for improvement in hospitals reporting higher rates of PRF.

The most widely used current measures of PRF are based on either claims data (CMS Patient Safety Indicator PSI 11) or proprietary registry data (National Surgical Quality Improvement Program (NSQIP) of the American College of Surgeons). The proposed eCQM is closely modeled after the NSQIP measure of PRF, which has been widely adopted across American hospitals, and is intended to complement and eventually supplant CMS PSI 11. As mentioned of section X.A.3.c.(3)(b) of the preamble of this proposed rule, these three MUC measures would potentially take the place of the CMS PSI 90 measure beginning in TEAM's second performance year. These three MUC measures will be available for optional reporting in the Hospital IQR Program beginning in 2026.

(4) Form, Manner, and Timing of Quality Measures Reporting

We believe it is important to be transparent and to outline the form, manner, and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine reconciliation payment amounts and repayment amounts. We propose that data submission for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health

[623] Mintz, J., Duprey, M. S., Zullo, A. R., Lee, Y., Kiel, D. P., Daiello, L. A., Rodriguez, K. E., Venkatesh, A. K., & Berry, S. D. (2022). Identification of Fall-Related Injuries in Nursing Home Residents Using Administrative Claims Data. The journals of gerontology. Series A, Biological sciences and medical sciences, 77(7), 1421–1429. *https://doi.org/10.1093/gerona/glab274.*

[624] Network of Patient Safety Databases Chartbook, 2022. Rockville, MD: Agency for Healthcare Research and Quality; September 2022. AHRQ Pub. No. 22–0051.

[625] National Quality Forum. Serious Reportable Events. *http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx.* Accessed July 24, 2019.

[626] WHO. (2009). Conceptual Framework for the International Classification for Patient Safety, Version 1.1. *https://apps.who.int/iris/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf.*

[627] Arozullah AM, Daley J, Henderson WG, Khuri SF. (2000). Multifactorial risk index for predicting postoperative respiratory failure in men after major noncardiac surgery. The National Veterans Administration Surgical Quality Improvement Program. Annals of surgery. 232(2):242–253.

[628] Arozullah AM, Daley J, Henderson WG, Khuri SF. (2000). Multifactorial risk index for predicting postoperative respiratory failure in men after major noncardiac surgery. The National Veterans Administration Surgical Quality Improvement Program. Annals of surgery. 232(2):242–253.

[629] Miller MR, Elixhauser A, Zhan C, Meyer GS. (2001). Patient Safety Indicators: using administrative data to identify potential patient safety concerns. Health services research. 36(6 Pt 2):110–132.

[630] Thompson SL, Lisco SJ. Postoperative Respiratory Failure. Int Anesthesiol Clin. 2018;56(1):147–164.

[631] Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. Neuro Oncol. 2013;15(11):1580–1588.

Record Data (CMIT ID #356), CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135), Hospital-Level, and Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMIT ID #1618) be accomplished through existing Hospital IQR Program processes. Since these measures are or will soon be reported to the Hospital IQR and HAC Reduction Programs, hospitals would not need to submit additional data for TEAM.

For the Measures Under Consideration (MUC) measures, Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (MUC2023–049), Hospital Harm—Postoperative Respiratory Failure (MUC2023–050) and Hospital Harm—Falls with Injury (MUC2023–048) measures, we would propose that data submission for these measures align with the Hospital IQR Program if they are finalized for that program as proposed. Similar to the proposed required measures noted previously, hospitals would not need to submit any additional data on these proposed measures if they are finalized and implemented for the Hospital IQR Program. We invite public comment on the proposal to collect quality measure data through the existing mechanisms of the Hospital IQR and HAC Reduction Program.

(5) Display of Quality Measures and Availability of Information for Public

We believe that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model. We propose to display quality measure results on the publicly available CMS website in a form and manner consistent with other publicly reported measures. CMS would share each TEAM participants' quality metrics with the hospital prior to display on the CMS website. The timeframe for when TEAM participants would receive data on our proposed measures align with the Care Compare schedule that can be found here: *https://data.cms.gov/provider-data/topics/hospitals/measures-and-current-data-collection-periods.* The Hybrid HWR and CMS PSI 90 measure results are posted annually in July. The THA/TKA PRO–PM is still in the voluntary reporting stage and the public reporting schedule for this measure will be reported on an annual basis. All measures under the statutory hospital quality programs have a 30-day preview period prior to results being posted on the Care Compare web page. TEAM participant measure scores will be delivered to TEAM participants confidentially. We propose to publicly report PY1 measure scores in 2027 and we would continue to publicly report scores every performance year with a one-year lag. TEAM has proposed 2027 as the first performance year for when scores will be publicly available due to the amount of lag time it takes for a few of our measures to fully process. For example, the Hybrid HWR measure which uses claims data and core clinical data elements from the EHR has about a year between from when the data is submitted and when that data is publicly posted. The applicable time periods for the measures during TEAM are summarized in the Table X.A.–05:

TABLE X.A.-05– SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF TEAM

Measure Title	TEAM Performance Year				
	1st	2nd	3rd	4th	5th
Hybrid Hospital-Wide Readmission Measure *	July 1, 2024 – June 30, 2025	July 1, 2025 – June 30, 2026	July 1, 2026 – June 30, 2027	July 1, 2027 – June 30, 2028	July 1, 2028 – June 30, 2029
CMS PSI 90 **	July 1, 2023 – June 30, 2025	July 1, 2024 – June 30, 2026	July 1, 2025 – June 30 - 2027	July 1, 2026 – June 30, 2028	July 1, 2027 – June 30, 2029
THA/TKA PRO-PM ***	July 1, 2024 – June 30, 2025	July 1, 2025 – June 30, 2026	July 1, 2026 – June 30, 2027	July 1, 2027 – June 30, 2028	July 1, 2028 – June 30, 2029

* Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356).
** CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135).
*** Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMIT ID #1618).

The proposed time periods for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356), CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135) and Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMIT ID #1618) are consistent with the Hospital IQR Program performance periods for the Hybrid HWR measure and THA/TKA PRO–PM and consistent with the HAC Reduction Program performance period for the CMS PSI 90 measure. We believe the public is familiar with the proposed measures, which have mostly been publicly reported in past releases of Care Compare as part of the Hospital IQR and HAC Reduction Programs. We are aware that the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) PRO–PM is new to the Hospital IQR Program, although it has been used in the CJR model for several years, and are seeking comment on the use of this measure for TEAM. To minimize confusion and facilitate access to the data on the measures included in TEAM, we propose to post the data on each TEAM participant's performance on each of the three proposed quality measures in a downloadable format in a section of the website specific to TEAM, similar to

what is done for the Hospital Readmissions Reduction Program and the HAC Reduction Program. We invite public comments on these proposals to post data for the required measures on the TEAM specific website.

d. Pricing and Payment Methodology

(1) Background

In determining the best methodology for setting target prices for episodes, we can draw on lessons learned from multiple iterations of both the CJR and BPCI Advanced target price methodologies. As we developed the methodologies for CJR and BPCI Advanced, and refined them over time in response to observed changes in nationwide spending trends and payment system changes (such as the removal of TKA and THA from the IPO list, and the reclassification of certain MS–DRGs), each new iteration drew from lessons learned in the previous iteration. For purposes of TEAM, we aim to find the balance between simplicity and predictive accuracy. CMS aims to choose a payment methodology that will be as transparent and understandable as possible for participants of varying levels of statistical background and knowledge; proposing calculations that are relatively straightforward and easy to explain would further this goal. On the other hand, the more elements we consider and more sophisticated statistical modeling we use, the better able we are to accurately predict performance period spending. Accurate performance period spending predictions increase the likelihood of achieving our model goals of setting target prices that provide a reasonable opportunity to achieve savings for Medicare but are not too onerous for participants.

(i) Previous Episode-Based Payment Methodologies

(A) CJR

When designing the CJR payment methodology, one goal was to be as simple and straightforward as possible, given that it was a mandatory model covering only one episode category. The initial CJR payment methodology included a 3-year baseline period that rolled forward every 2 years. Target prices used a blend of participant-specific and regional spending, which shifted towards 100% regional spending for PY 4–5. Downside risk was waived for the first performance year of the model to allow participants time to enact practice changes that would help them succeed in the model. Beginning in PY 2, participants were subject to both upside and downside risk, within stop-loss and stop-gain limits that increased to a maximum of 20% by PY 3 for most hospitals. The stop-loss and stop-gain limits were designed to ensure that participants would neither be subject to an unmanageable level of risk, nor be incentivized to stint on care to achieve savings. The initial CJR payment methodology is described in detail in the final rule titled ''Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Service'' that appeared in the November 24, 2015 **Federal Register** (80 FR 73274) (referred to in this proposed rule as the ''2015 CJR Final Rule''), starting at 80 FR 73324.

The initial CJR payment methodology was modified in the final rule titled ''Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Medicare and Medicaid Programs; Policies and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' that appeared in the May 3, 2021 **Federal Register** (86 FR 23496) (referred to in this proposed rule as the ''2021 CJR 3-Year Extension Final Rule''). The CJR model's 3-year extension and modification was due to a number of factors, as described in detail starting at 86 FR 23508. A principal reason for the modifications to the payment methodology was the fact that the initial CJR target price methodology did not account for changing downward trends in spending on LEJR episodes, both among CJR participant hospitals and non-participant hospitals. The resulting reconciliation payments under the initial methodology rewarded participants for spending reductions that likely would have happened regardless of the model, which led to concerns that target prices could be too high for Medicare to achieve savings in the model over time.

The changes to the model increased the complexity in some ways (for example, the addition of risk adjustment multipliers) while simplifying it in other ways (for example, the removal of update factors) in order to calculate target prices that would more accurately reflect performance period spending. A retrospective Market Trend Factor was applied to target prices at reconciliation to capture changes in spending patterns that occurred nationally during the performance period. This market trend factor, in combination with the change from a 3-year baseline to a 1 year baseline, negated the need for setting-specific update factors that we had used previously to set purely prospective target prices. At the same time, our added risk adjustment increased target prices for episodes with more complex patients, to better reflect the higher costs associated with those patients. The changes to the CJR payment methodology are described in detail in the 2021 CJR 3-Year Extension Final Rule starting at 86 FR 23508.

(B) BPCI Advanced

By contrast, the BPCI Advanced methodology is more complex. The target price calculation method was designed to support participation from a broad range of providers by accounting for variation in episode payments and factors that contribute to differences that are beyond providers' control. In Model Years 1–3, BPCI Advanced target prices were constructed using a 4-year rolling baseline period and were based on hospital historical payments, patient risk adjustment, a prospective peer group trend factor, and 3% CMS discount. PGP target prices adjusted hospital target prices for PGP-specific patient case mix and differences between PGP and hospital historical payments. Risk adjustment is performed using a 2-stage model, with Stage 1 consisting of a compound log-normal model with episode cost as the dependent variable, and Stage 2 consisting of an Ordinary Least Squares regression with case mix adjusted spending as the dependent variable.

The use of a prospective trend in Model Years 1–3 resulted in prices not accurately predicting spending that arose from unanticipated, systematic factors. For example, changes in coding guidelines can lead to cost changes. In fiscal year 2017, there were changes to the guidelines for coding the congestive heart failure (CHF) and simple pneumonia episodes, two of the highest-volume episodes in the BPCI Advanced model. The change resulted in an increase in the share of patients classified as having more serious CHF and simple pneumonia diagnoses in the performance period than in the baseline period. Because target prices are based on the seriousness of a patient's diagnosis, target prices increased leading to larger reconciliation payments to participants and losses to Medicare.

The losses to Medicare spurred changes to the BPCI Advanced pricing methodology. Similar to CJR, the prospective trend factor used in Model Years 1–3 was replaced in Model Year 4 with a retrospective trend factor adjustment at reconciliation, although this retrospective trend adjustment was

subject to guardrails. Specifically, the trend at reconciliation could not exceed +/−10% of the prospective trend for Model Years 4 and 5, and in response to participant feedback, the trend adjustment was limited to +/−5% beginning in Model Year 6. The CMS discount was also reduced in Model Year 6 from 3% to 2% for medical episodes. Pricing methodology changes since Model Year 4 were intended to improve pricing accuracy and reflect actual spending trends during the performance period. Future evaluation reports will assess the effectiveness of these changes. Additional information on the BPCI Advanced pricing methodology may be found on the BPCI Advanced participant resources page.[632]

In TEAM, our goal is a target price methodology that blends the most successful elements of each of these model iterations, striking a balance of predictability and accuracy.

(2) Overview of TEAM Pricing and Payment Methodology

While we describe each element of the pricing and payment methodology in detail in the following sections, here we present an overview of the proposed TEAM pricing and payment methodology. At proposed § 512.540, we are proposing to use3 years of baseline data, trended forward to the performance year, to calculate target prices at the level of MS–DRG/HCPCS episode type and region. We propose to group episodes from the baseline period by applicable MS–DRG for episode types that include only inpatient hospitalizations, and by applicable MS–DRG or HCPCS code for episode types that include both inpatient hospitalizations and outpatient procedures. For episodes types that include both inpatient hospitalizations (identified by MS–DRGs) and outpatient procedures (identified by HCPCS codes), HCPCS codes are combined for purposes of target pricing with the applicable MS–DRG representing an inpatient hospitalization without Major Complications and Comorbidities, as we expect those beneficiaries to have similar clinical characteristics and costs. After capping high-cost outlier episodes at the 99th percentile for each of the 24 proposed MS–DRG/HCPCS episode types and 9 regions (which we propose at proposed § 512.505 to define as the 9 U.S. census divisions, as defined by the U.S. Census Bureau), we propose to use average standardized spending for each MS–DRG/HCPCS episode type in each region as the benchmark price for that MS–DRG/HCPCS episode type for that specific region, resulting in 216 MS–DRG/HCPCS episode type/region-level benchmark prices. We propose to apply a prospective trend factor and a discount factor to benchmark prices (as well as a prospective normalization factor, described later in this section) to calculate preliminary target prices. The prospective trend factor would represent expected changes in overall spending patterns between the most recent calendar year of the baseline period and the performance year, based on observed changes in overall spending patterns between the earliest calendar year of the baseline period and the most recent year of the baseline period. The discount factor would represent Medicare's portion of potential savings from the episode.

At proposed § 512.545, we propose to risk adjust episode-level target prices at reconciliation by the following beneficiary-level variables: age group, Hierarchical Condition Category count (a measure of clinical complexity), and social risk (the components of which are described in more detail in sections X.A.3.d.(4) and X.A.3.f of the preamble of this proposed rule). We propose to calculate risk adjustment multipliers prospectively at the MS–DRG/HCPCS episode type level based on baseline data and hold those multipliers fixed for the performance year. To ensure that risk adjustment does not inflate target prices overall, we further propose to calculate a prospective normalization factor based on the data used to calculate the risk adjustment multipliers. We propose to apply the prospective normalization factor, in addition to the prospective trend factor and discount factor described previously, to the benchmark price to calculate the preliminary target price for each MS–DRG/HCPCS episode type and region. We propose that the prospective normalization factor would be subject to a limited adjustment at reconciliation based on TEAM participants' observed performance period case mix, such that the final normalization factor would not exceed +/−5% of the prospective normalization factor.

(3) Target Prices

(a) Baseline Period for Benchmarking

At proposed § 512.540(b)(2) we propose to use 3 years of baseline episode spending to calculate benchmark prices, which we would further adjust as described in section X.A.3.d.(3)(i) of the preamble of this proposed rule to create preliminary target prices. We propose to roll this 3-year baseline period forward every year. Specifically, we propose that—

- To determine baseline episode spending for PY1, CMS would use baseline episode spending for episodes that started between January 1, 2022 and December 31, 2024;
- To determine baseline episode spending for PY2, CMS would use baseline episode spending for episodes that started between January 1, 2023 and December 31, 2025;
- To determine baseline episode spending for PY 3, CMS would use baseline episode spending for episodes that started between January 1, 2024 and December 31, 2026;
- To determine baseline episode spending for PY 4, CMS would use baseline episode spending for episodes that started between January 1, 2025 and December 31, 2027;
- To determine baseline episode spending for P Y 5, CMS would use baseline episode spending for episodes that started between January 1, 2026 and December 31, 2028.

The use of 3 years of baseline episode spending is consistent with our initial CJR methodology, as described in the 2015 CJR Final Rule at 80 FR 73340. In that case, the 3-year baseline period moved forward every 2 years. However, in combination with the lack of a retrospective trend factor, the use of a 3-year baseline period that only moved forward every 2 years meant that our methodology was not able to capture the degree to which spending on LEJR episodes was decreasing nationwide, both among CJR and non-CJR hospitals. As a result, we believe our target prices partially reflected spending decreases that were not due specifically to participation in CJR.

Subsequently, in the 2021 CJR 3-Year Extension Final Rule, we finalized a policy to use a 1-year baseline period that would move forward every year (with the exception of skipping data from 2020 due to COVID–19 irregularities) (86 FR 23514). In combination with a retrospective market trend factor, using 1 year of baseline episode spending updated every year meant that our target prices would not be inflated as they had been under the initial CJR methodology. BPCI Advanced employs a strategy that blends elements of both CJR approaches, with a longer baseline period (4 years) similar to the initial CJR methodology, but shifting forward every year, as we do in the CJR extension.

Participants in episode-based payment models have expressed concerns about a concept known as the ''ratchet effect'' when choosing the baseline period from which to calculate

[632] *https://www.cms.gov/priorities/innovation/innovation-models/bpci-advanced/participant-resources.*

target prices. That is, participants do not want to be penalized for achieving lower spending by having lower target prices in subsequent years. The use of fewer years of the most recent baseline episode spending, as well as more frequent rebasing, will generally decrease target prices more quickly year over year if overall episode spending is decreasing, as opposed to a longer, fixed baseline. However, we need to balance this concern against the likelihood of having inaccurate target prices if we use older baseline episode spending or rebase less frequently.

One way that we propose to mitigate the ratchet effect is that we propose to use a 3-year baseline period and rebase annually. We believe this approach would achieve a balance between having target prices based on sufficiently up-to-date spending patterns but not requiring participants to compete against only the most recent spending patterns.

We propose to adjust baseline episode spending to trend all episode spending to the most recent year of the baseline period. The adjustment would reflect the impact of inflation and any changes in episode spending due to evolving patterns of care, Medicare payment policies, payment system updates, and other factors during the baseline period. We propose to define a baseline year as any of the three CYs during a given baseline period. For example, baseline year 1 for PY 1 will be CY 2022, baseline year 2 will be CY 2023, and baseline year 3 will be CY 2024. We propose to calculate the adjustment factors for baseline years 1 and 2 by dividing average episode spending for baseline year 3 episodes by average episode spending for episodes from baseline years 1 and 2, respectively. We would then apply the applicable adjustment factors to the episode spending of each episode in baseline years 1 and 2. This adjustment would bring all baseline episode spending forward to the most recent baseline year, so that baseline year 1 and 2 spending would be expressed in baseline year 3 dollars. This method would be consistent with how we calculated the baseline trend factor for CJR in the performance years that used the 3-year baseline period, as described in the 2015 CJR Final Rule (80 FR 73342). We propose to calculate these baseline trend factor adjustments at the MS–DRG/HCPCS episode type and region level.

In recognition of the fact that baseline episode spending from more recent years are likely to be a better predictor of performance year spending, we propose to weight recent baseline episode spending more heavily than episode spending from earlier baseline years. Specifically, we propose to weight episode spending from baseline year 1 at 17%, baseline year 2 at 33%, and baseline year 3 at 50%. This method of weighting would mean that the most recent episode spending patterns, expected to be the most accurate predictor of performance year spending, would contribute most strongly to the benchmark price at 50%. The remaining 50% would be divided into thirds, with baseline year 2 contributing approximately ⅔, while baseline year 1, which is likely to be the least accurate predictor of performance year spending, would contribute ⅓.

We seek comment on our proposal at proposed § 512.540(b)(2–3) to use 3 years of baseline episode spending, rolled forward for each performance year, with more recent baseline years weighted more heavily, to calculate TEAM target prices.

(b) Regional Target Prices

We are proposing to provide to TEAM participants target prices for each proposed MS–DRG/HCPCS episode type and region based on 100% regional data for all TEAM participants prior to each PY. This approach would be consistent with PY 4–8 of CJR. While CJR target prices used a blend of ⅔ hospital-specific data and ⅓ regional data for PY 1–2, and ⅓ hospital-specific data and ⅔ regional data for PY 3, we stated our reasons in the 2015 CJR Final Rule for moving towards fully regional target pricing as participants gained more experience in the model (80 FR73347). Target prices based on hospital-specific data would require a TEAM participant to compete against its own previous performance, such that improvement over previous performance would result in a reconciliation payment. Conversely, target prices based on regional data would require a TEAM participant to compete against its peers in that region, such that only a specific level of achievement, as opposed to improvement alone, would result in a reconciliation payment. For TEAM participants that are historically inefficient compared to their peers, hospital-specific target prices would be higher than regional target prices because hospital-specific baseline episode spending would be greater than average baseline episode spending for the region. For TEAM participants that are historically efficient compared to their peers, hospital-specific target prices would be lower than regional target prices because hospital-specific baseline episode spending would be lower than average baseline episode spending for the region. We noted in the 2015 CJR Final Rule that if we used 100% hospital-specific pricing in CJR, historically efficient hospitals could have fewer opportunities for achieving additional efficiencies under the model and would not be rewarded for maintaining high quality and efficiency, whereas less efficient hospitals would be rewarded for improvement even if they did not reach the same level of high quality and efficiency as the more historically efficient hospitals. However, as described in section X.A.3.f of the preamble of this proposed rule, health equity has been a priority in the proposed design of TEAM. We are concerned by literature stating that safety net hospitals in CJR were disproportionately likely to owe a repayment once we moved to 100% regional pricing.[633] [634] We note that these findings reflect the original CJR payment methodology, which did not include risk adjustment at the beneficiary level. For PY 6–8, the modified CJR payment methodology incorporates beneficiary level risk adjustment, including an adjustment for dual income eligibility. Additionally, although we provided lower stop-loss limits for rural and low-volume hospitals, we did not identify or provide protective stop-loss limits for safety net hospitals.

Therefore, in addition to lower stop-loss limits for Track 1 and Track 2 TEAM participants as compared to Track 3 TEAM participants, and the incorporation of additional measures of social need in our beneficiary-level risk adjustment, we considered an alternative target price proposal to provide Track 1 and Track 2 TEAM participants with 100% hospital-specific, rather than regional, target prices. However, given our proposal to calculate target prices at the MS–DRG/HCPCS episode type level, we are concerned that many Track 1 or Track 2 TEAM participants would not meet the low volume threshold of baseline episodes to calculate reliable target prices for many of the MS–DRG/HCPCS episode types included in TEAM. Additionally, there may be some hospitals that serve a high proportion of underserved populations, yet have already achieved high levels of quality and efficiency, such that a 100%

[633] Carey, K., & Lin, M–Y. (2022). Safety-net hospital performance under Comprehensive Care for Joint Replacement. Health Services Research, 2022(1–6). *https://doi:10.1111/1475-6773.14042*.

[634] Shashikumar, S.A., Ryan, A.M., & Joynt Maddox, K.E. (2022). Equity implications of hospital penalties during 4 years of the Comprehensive Care for Joint Replacement Model, 2016 to 1019. JAMA Health Forum, 3(12). *https://doi.org/10.1001/jamahealthforum.2022.4455*.

hospital-specific target price would be disadvantageous.

We also considered blending hospital-specific pricing with regional pricing as we did in the first 3 years of CJR. For instance, we considered using a blend of 50% hospital-specific data and 50% regional data to calculate target prices for Track 1 and Track 2 participants. We further considered using a different blend for Track 1 and Track 2 participants vs. Track 3 participants. For example, we considered using a blend of ⅔ hospital-specific data and ⅓ regional data for Track 1 and Track 2 participants, and a blend of ⅓ hospital-specific data and ⅔ regional data for Track 3 hospitals. However, blending hospital-specific pricing with regional pricing could be subject to the same concerns regarding low volume or disadvantaging efficient hospitals as 100% hospital-specific pricing, though to a lesser degree.

We also considered, but are not proposing, calculating target prices at the region/episode category level as compared to our proposed region/MS–DRG/HCPCS level. Calculating target prices at the region/episode category would help to mitigate some concerns with certain MS–DRG/HCPCS episode types having a low volume of episodes in a given region. However, to ensure target prices are sufficiently risk-adjusted to capture spending differences between the different MS–DRG/HCPCS within a given episode category, we considered including MS–DRG/HCPCS risk adjusters in TEAM's risk adjustment methodology if we calculated target prices at the region/episode category level. We seek comment on calculating target prices at the region/episode category level.

We seek comment on our proposal at proposed § 512.540(b)(1) to provide regional target prices to all TEAM participants for each PY during the model performance period. We also seek comment on other potential ways to set target prices for Track 1 or Track 2 TEAM participants, including adjustments to regional target prices for Track 1 or Track 2 TEAM participants, that would decrease the likelihood of safety net hospitals being disproportionately penalized by regional target prices.

(c) Services That Extend Beyond an Episode

As we are proposing a fixed 30-day post discharge episode length as discussed in section X.A.3.b.(5)(d) of the preamble of this proposed rule, we recognize that there may be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in an episode who is admitted to a SNF for 15 days, beginning on Day 26 post-discharge from the TEAM anchor hospitalization or anchor procedure. The first 5 days of the SNF admission would fall within the episode, while the subsequent 10 days would fall outside of the episode.

We propose that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we propose to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. For HHA services that extend beyond the episode, we propose that the payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the episode. This proposed policy would ensure that TEAM participants are not held responsible for the cost of services that did not overlap with the episode period.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we propose to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations, called the normal MS–DRG payment amount for purposes of this proposed rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS final rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS final rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30-day post-episode payment calculation discussed in section X.A.3.(d)(5) of the preamble of this proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

This methodology would be consistent with CJR, and is described as applied to CJR in the 2015 CJR Final Rule (80 FR 73333). We seek comment on our proposed methodology at proposed § 512.555 for prorating services that extend beyond the episode.

(d) Episodes That Begin in One Performance Year and End in the Subsequent Performance Year

Given that we are proposing episodes with a 30-day post discharge period, we recognize that some episodes will begin during one performance year and end during the following performance year. We propose that all episodes would receive the target price associated with the date of discharge from the anchor hospitalization or the anchor procedure, as applicable, regardless of the episode end date, which determines the performance year in which the episode would be reconciled. We note that the assignment of target prices based on the date of discharge from the anchor hospitalization or the anchor procedure is different from CJR, where the target price was assigned based on the episode start date rather than the discharge date, but it is consistent with BPCI Advanced. As noted in section X.A.3.d.(5)(a) of the preamble of this proposed rule, annual reconciliation is based on episodes that end during a PY, so if an episode extends past the end of a PY, that episode would factor into the next PY's reconciliation, when the episode ends, which is consistent with both CJR and BPCI Advanced. Accordingly, if an episode were to end after the final performance year of the model, we propose that it would not be reconciled. We seek comment on our proposal at proposed § 512.540(a)(3) for applying target prices to an episode that begins in one performance year and ends in the subsequent performance year.

(e) High-Cost Outlier Cap

Given the broad proposed episode definition and 30-day proposed post-discharge period, we want to ensure that hospitals have some protection from the downside risk associated with especially high payment episodes,

where the clinical scenarios for these cases each year may differ significantly and unpredictably. As we stated in the 2015 CJR Final Rule (80 FR 73335), we do not believe that the opportunity for a hospital's systematic care redesign of particular surgical episodes has the significant potential to impact the clinical course of these extremely disparate high payment cases. In the 2015 CJR Final Rule (80 FR 73335) we finalized a policy to limit the hospital's responsibility for high episode payment cases by utilizing a high price payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices. This policy was designed to prevent participant hospitals from being held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent. The policy, and the reasoning behind it, is described in detail at (80 FR 73335).

However, as we described in 86 FR 23518, based on data from the first few years of the CJR model, we observed that the original 2 standard deviation methodology was insufficient to identify and cap high episode spending, as more episodes than expected exceeded the spending cap. We describe in detail our reasoning for finalizing a change to the high episode spending cap in the 2021 CJR 3-Year Extension Final Rule (86 FR 23518). We finalized a change to the calculation of the high episode spending cap to derive the amount by setting the high episode spending cap at the 99th percentile of historical costs for each MS–DRG for each region. The resulting methodology was similar to the BPCI Advanced methodology for capping high-cost episode spending at the 99th percentile for each MS–DRG.

We propose a similar high-cost outlier policy for TEAM. We propose to cap both baseline episode spending and performance year episode spending at the 99th percentile of spending at the MS–DRG/HCPCS episode type and region level, referred to as the high-cost outlier cap. We propose to determine the 99th percentile of spending at the MS–DRG/HCPCS episode type and region level during the applicable time period, and then set spending amounts that exceed the high-cost outlier cap to the amount of the high-cost outlier cap. For instance, if the high-cost outlier cap was set at $30,000, an episode that had actual episode spending of $45,000 would have its spending amount, for purposes of the model, reduced by $15,000 when the cap was applied and therefore, the spending for that episode would be held at $30,000. We propose to use capped episode spending when calculating benchmark prices in order to ensure that high-cost outlier episodes do not artificially inflate the benchmark. When calculating performance year episode spending at reconciliation, we propose to use capped episode spending so that a TEAM participant would not be held responsible for catastrophic episode spending amounts that they could not reasonably have been expected to prevent. We seek comment on our proposal at proposed § 512.540(b)(4) for calculating and applying the high-cost outlier cap.

(f) Trending Prices

Target prices are derived from a prediction based on previous Medicare spending patterns, but it is not possible to perfectly predict how Medicare spending patterns may change over the course of the performance year. In the original BPCI model, prospective target prices were not provided to participants, so the trend factor was calculated retrospectively based on the observed spending during the performance period. Quarterly reconciliations in BPCI meant that participants could gain a sense of how their target prices tended to change over time and get relatively frequent feedback on their performance in the model. However, BPCI participants did not like the uncertainty of not knowing their target prices in advance.

In the initial CJR methodology and Model Years 1–3 of BPCI Advanced, CMS provided fully prospective target prices to participants. Participants appreciated the certainty of prospective target prices, where we predict in advance how spending patterns might shift and hold those target prices firm even if we underpredicted or overpredicted spending. This methodology included applying update factors to account for setting-specific payment system updates, allowing us to estimate how a given set of services performed during the baseline would be priced had those same services been subject to the fee schedules in effect during the performance period.

In CJR, we originally overpredicted performance period spending, not accounting for the overall decline in spending on LEJR episodes nationwide that occurred outside of the model during its first few performance years. In BPCI Advanced, we similarly overpredicted performance period spending for certain episodes because our methodology was unable to account for medical coding changes that occurred between the baseline and performance period, or during the performance period itself. For instance, in FY 2016, changes to medical coding guidance were made for Inpatient Congestive Heart Failure, such that certain patients who during the baseline would have been coded as the less expensive MS–DRG 292, were instead coded as the more expensive MS–DRG 291, in spite of having the same clinical characteristics. This meant that many beneficiaries who received a target price associated with the more expensive MS–DRG 291, actually had the lower performance period costs previously associated with the less expensive MS–DRG 292. The use of a fully prospective trend factor was unable to capture these changes in both practice patterns and coding guidelines.

Subsequently, we modified both models' methodologies to include a retrospective trend adjustment. Starting in Model Year 4, we continued to provide BPCI Advanced participants with a prospective target price using an estimated trend factor, but we adjusted the target price at reconciliation based on the retrospective calculation of the trend factor using performance period data. Initially, this policy included guardrails around the magnitude of the retrospective trend factor adjustment of +/−10%. In response to participant feedback, we lowered the maximum level of the retrospective trend factor adjustment to +/−5% starting in Model Year 6.

In the CJR extension, the retrospective trend is known as the market trend factor adjustment. It is fully retrospective and calculated at reconciliation, meaning that the unadjusted target price we post on the CJR website prior to the performance year does not include a prospective trend factor. In response to participant requests, we provided estimates of the market trend factor on the CJR website based on the most recently available data to help participants estimate their potential target prices. The market trend factor is calculated separately for each MS–DRG/region combination. For the PY 6 reconciliation (corresponding to episodes that ended between October 1, 2021 and December 31, 2022), the highest market trend factor was 1.294 for MS–DRG 469 episodes in the West South Central region, while the lowest market trend factor was 0.972 for MS–DRG 521 episodes in the New England region.

For TEAM, we are proposing to provide preliminary target prices that incorporate a prospective trend factor to TEAM participants. We propose at § 512.540(b)(7) to calculate this prospective trend factor as the percent difference between the average regional

MS–DRG/HCPCS episode type expenditures computed using the most recent year of the applicable baseline period, and the comparison average regional MS–DRG/HCPCS episode type expenditures during the first year of the baseline. By comparing baseline year 3 to baseline year 1, the prospective trend would capture changes across a two-year period, which we believe is appropriate given that we would be projecting spending patterns in the performance year which would be 2 years after baseline year 3. This proposed trend factor calculation would be similar to how the market trend factor is currently calculated in the CJR extension, but instead of retrospectively comparing average regional MS–DRG/HCPCS episode type spending during the performance year to spending during the baseline year, the calculation would be performed prospectively, so that performance year expenditures would not be considered. A fully prospective trend factor would give participants more certainty about what their reconciliation target prices would be, although reconciliation target prices as proposed would incorporate both beneficiary-level risk adjustment and an adjustment to the prospective normalization factor, as applicable (as described in section X.A.3.d.(4) of the preamble of this proposed rule).

Given our proposal to use a prospective trend factor to predict future spending for the purposes of pricing stability, we considered but are not proposing to include update factors that take into account Medicare payment systems updates for each fiscal year (FY) or calendar year (CY) and could improve pricing accuracy. Specifically, we considered a methodology similar to BPCI Advanced and Performance Years 1–5 of CJR, where preliminary target prices are updated to reflect the most current FY and CY payment system rates using setting-specific update factors for payment system, including the IPPS, the OPPS, the Physician Fee Schedule (PFS), the Home Health Prospective Payment System (HH PPS), the Medicare Economic Index (MEI), the Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS), and the Skilled Nursing Facility (SNF) PPS. However, updating target prices using setting-specific update factors would result in TEAM participants receiving more than one target price for a MS–DRG/HCPCS episode type in a performance year which can increase complexity. Further, while including update factors would generally increase target prices, it also decreases pricing stability since the preliminary target price would change due to the application of update factors. We seek comment on whether we should include setting-specific update factors in preliminary target prices to improve pricing accuracy, or if there are other ways we should consider updating target prices that would reflect Medicare payment system updates.

We considered, but are not proposing, an alternative proposal to adjust the preliminary target price at reconciliation based on the observed trend during the performance year. We considered proposing to limit the magnitude of this retrospective trend adjustment by applying guardrails, similar to what we currently do in BPCI Advanced. Specifically, if the trend factor calculated at reconciliation based on performance year expenditures differed from the prospective trend factor by up to +/−5%, we considered proposing to adjust the preliminary target price at reconciliation by applying the final trend factor to the baseline target price. If the final trend factor differed from the prospective trend factor by more than +/−5%, we considered proposing to only adjust the preliminary target price by +/−5%. In other words, we considered proposing that the maximum upward trend adjustment we would make to the preliminary target price at reconciliation would be 5%, and the maximum downward trend adjustment we would make to the preliminary target price at reconciliation would be −5%. We also considered lower percentages for the guardrails, including 3% and 1%, given the BPCI Advanced model's experience initially having a higher percentage maximum adjustment and then reducing the percentage in later years of the model. We considered these alternative proposals because we believed that these guardrails would help us achieve a balance of providing predictability to participants and mitigating the risk that target prices would be disproportionately impacted by performance year shifts in spending patterns that could not have been foreseen.

We are also requesting comment on alternative ways to calculate the trend factor to both increase accuracy of prospective target prices and to mitigate the ratchet effect. We recognize that spending on some episodes, such as Lower Extremity Joint Replacement, has been decreasing over time and may reach a point where further decreases in spending could compromise quality and patient safety. While in the early years of CJR, our target prices failed to account for decreasing trends in spending for LEJR nationwide and thus were overinflated, that downward trend has since stabilized, suggesting that there may no longer be as much of an opportunity for participant savings as there was in the early years of CJR. In the case of an episode where spending has been decreasing but has since stabilized, trending the target price forward based on previous years' trends could result in target prices that are too low. In such a scenario, a retrospective trend adjustment might actually result in a higher target price than a fully prospective trend. We are seeking comment on ways to construct a trend factor that can result in a reasonable target price regardless of whether spending has been increasing, decreasing, or stabilizing.

For example, in the CY 2023 Physician Fee Schedule final rule, CMS finalized a policy to include a prospectively-determined component, the Accountable Care Prospective Trend (ACPT), in the factor used to update the benchmark to the performance year for ACO agreement periods starting on or after January 1, 2024 (see 87 FR 69881 to 69898) to help address the ratchet effect by insulating a portion of the update factor from the impact that ACO savings can have on retrospective national and regional spending trends. This type of trend is referred to as an administrative trend, because it is not directly linked to ongoing observed FFS spending. However, we recognize that there may be some concerns using administrative trends for episode-based payment models, as opposed to population-based payment models like ACOs, because administrative trends may not capture episode-specific trends, which could lead to higher or lower preliminary target prices when compared to actual performance year spending. We request comment on this type of trending approach, or other potential ways to increase the accuracy of prospective target prices and mitigate the ratchet effect when we update TEAM target prices.

We seek comment on our proposal at proposed § 512.540(b)(7) for calculating and applying a prospective trend factor.

(g) Discount Factor

In addition to the prospective trend factor, at proposed § 512.540(c) we propose to apply a discount factor to the benchmark price when calculating preliminary target prices. Specifically, we propose to apply a 3% discount factor to the benchmark price to serve as Medicare's portion of reduced expenditures from the episode. This discount would be similar to the 3% discount factor applied to target prices

in the CJR model and to surgical episode target prices in BPCI Advanced.

However, we recognize that there may be different levels of opportunity for savings within different episode types. For instance, in BPCI Advanced, in recognition of the fact that participants were generally able to achieve greater savings in surgical, as opposed to medical, episodes, we incorporated a 3% discount into surgical episode target prices and a 2% discount into medical episode target prices. Given differential opportunities for savings across the different types of proposed episode categories, as well as our intention to incorporate additional episodes in future years of TEAM, we considered but are not proposing varying the Medicare discount based on episode category. Specifically, we considered but are not proposing lower discount factors including 2%, 1%, 0.5%, or no discount factor. We also considered linking the discount to variability in episode spending during the baseline, such that an episode with minimal variability in baseline spending might have a lower discount percentage, given that lower variability in baseline spending might indicate fewer opportunities for savings in that episode, as opposed to episodes with greater spending variability. We also considered but are not proposing lower discount factors, including 2%, 1%, 0.5%, or no discount factor, for specific types of TEAM participants. For example, we considered no discount factor for safety net hospitals given the proportion of underserved beneficiaries they care for and many of these safety net hospitals may be new to episode-based payment participation. Although we are not proposing these alternatives, we seek comment on whether we should include any of these alternatives in TEAM and also seek comment on different ways to adjust the Medicare discount based on differential savings opportunities for different episode types.

We seek comment on our proposal at proposed § 512.540(c) to apply a 3% discount factor to preliminary episode target prices for episodes.

(h) Special Considerations for Low Volume Hospitals

In both CJR and BPCI Advanced, we recognized that hospitals that perform a number of episodes below a certain volume threshold would have insufficient volume to receive a target price based on their own baseline data. In the 2015 CJR Final Rule (80 FR 73285), we acknowledged that such hospitals might not find it in their financial interests to make systemic care redesigns or engage in an active way with the CJR model. At 80 FR 73292, we acknowledged commenter concerns about low volume providers, including but not limited to, observations that low volume providers could be less proficient in taking care of LEJR patients in an efficient and cost-effective manner, more financially vulnerable with fewer resources to respond to the financial incentives of the model, and disproportionately impacted by high-cost outlier cases. In spite of these potential challenges, we stated that the inclusion of low volume hospitals in CJR was consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances (80 FR 73292).

In CJR, we set the low volume threshold as fewer than 20 CJR episodes across the 3-year baseline years of 2012–2014. Low volume hospitals received target prices based on 100% regional data, rather than a blended target price that incorporated their participant-specific data, because a target price based on limited data is less likely to be accurate and reliable. These hospitals were also subject to the lower stop-loss limits that we offered to rural hospitals, in recognition of the fact that they might be less prepared to take on downside risk than hospitals with higher episode volume. In the CJR 2017 Final Rule that reduced the number of mandatory MSAs, low volume hospitals were among the types of hospitals that were required to opt in if they wanted to remain in the model (82 FR 57072). In the 2020 Final Rule, we removed the remaining low volume hospitals from the CJR extension when we limited the CJR participant hospital definition to those hospitals that had been mandatory participants throughout the model (86 FR 23497).

In BPCI Advanced, our low volume threshold policy was to not provide a target price for a given clinical episode category if performed at a hospital that did not meet the 41 clinical episode minimum volume threshold during the 4-year baseline period. This meant that no BPCI Advanced episodes would be triggered for that particular clinical episode category during the applicable performance period at that hospital. However, participants could continue to trigger other clinical episode categories for which they had enrolled and for which there was sufficient baseline volume. Additionally, clinical episodes that occurred at the hospital during the performance period, though not triggering a BPCI Advanced episode, would count toward the low volume threshold when that year became part of the baseline. Therefore, as the baseline shifted forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and receive a target price for the clinical episode category for a subsequent performance period.

In TEAM, we propose that there will be a low volume threshold for purposes of reconciliation. This low volume threshold would apply to total episodes across all episode categories in the baseline period for a given PY. If a TEAM Participant did not meet the proposed low volume threshold of at least 31 total episodes in the baseline period for PY1, CMS would still reconcile their episodes, but the TEAM participant would be subject to the Track 1 stop-loss and stop-gain limits for PY1. If a TEAM Participant did not meet the proposed low volume threshold of at least 31 total episodes in the applicable baseline periods for PYs 2–5, the TEAM Participant would be subject to the Track 2 stop-loss and stop-gain limits for PY 2–5, as described in section X.A.3.d.(5)(h) of the preamble of this proposed rule.

We considered, but are not proposing, including alternative approaches to a minimum episode volume threshold in TEAM, including an approach similar to BPCI Advanced, where if a TEAM participant did not meet the 31 episode minimum volume threshold for a given episode category in the 3-year baseline period, the TEAM participant would not be held accountable for that episode category for the performance year that aligned with the 3-year baseline period. We also considered different minimum volume thresholds in the baseline period, including 51, 21, and 11. However, we are concerned that imposing a minimum volume threshold that removes TEAM participant accountability may restrict the number of hospitals eligible to participate in TEAM and limit beneficiary access to the benefits of value-based, coordinated care. We also considered implementing minimum episode volume thresholds during the performance year. Specifically, we considered not holding TEAM participants accountable for a given episode category if they initiated less than 11 or 6 episodes in a given episode category or less than 31 or 21 total episodes across episode categories in a performance year. However, we are concerned that including minimum episode volume thresholds during the performance year may introduce program integrity issues where TEAM

participants steer TEAM beneficiaries to other providers to be below the threshold and not be accountable for episodes in TEAM. We seek comment on whether TEAM should consider implementing the alternatives to the minimum volume thresholds for either the 3-year baseline period or the performance year.

We seek comment on our proposal at proposed § 512.550(e)(3) for setting and applying the low volume threshold at reconciliation.

(i) Preliminary Target Prices

We propose that CMS would provide preliminary target prices to TEAM participants prior to the start of each performance year. For instance, since the earliest episodes for a given performance year would end on January 1, and most of these episodes would have been initiated by an anchor hospitalization or anchor procedure that occurred near the end of November or the beginning of December of the previous calendar year, we propose to provide preliminary target prices to the TEAM participant by the end of November prior to each performance year. We propose that preliminary target prices would be based on regional episode spending during the baseline period. TEAM participants would receive the preliminary target prices for each MS–DRG/HCPCS episode type that corresponded to their region. We propose that these preliminary target prices would incorporate a prospective trend factor (as described in section X.A.3.d.(3)(f) of the preamble of this proposed rule) and a discount factor (as described in section X.A.3.d.(3)(g) of the preamble of this proposed rule), as well as a prospective normalization factor (as described in section X.A.3.d.(4) of the preamble of this proposed rule) that would be subject to limited adjustment at reconciliation (as described in section X.A.3.d.(5)(h) of the preamble of this proposed rule).

(4) Risk Adjustment and Normalization

In the original CJR methodology, we first proposed that risk adjustment be limited to providing separate target prices for episodes initiated by MS–DRG 469 versus MS–DRG 470, because MS–DRGs under the IPPS are designed to account for some of the clinical and resource variations that exist and that impact hospitals' costs of providing care (80 FR 73338). In response to comments requesting further risk adjustment, in the 2015 CJR Final Rule we finalized a policy to risk adjust target prices based on the presence of hip fractures in order to capture a significant amount of patient-driven episode expenditure variation (80 FR 73339). As a result, we provided four separate target prices to participant hospitals based on MS–DRG 469 versus MS–DRG 470, and presence versus absence of a primary hip fracture. The impact of hip fractures on inpatient costs associated with a hip replacement was subsequently acknowledged by CMS' decision to create two new MS–DRGs (521 and 522) for hip replacements in the presence of a primary hip fracture (85 FR 58432). We incorporated these new MS–DRGs into the CJR model episode definition as of October 1, 2020 via the November 2020 Interim Final Rule with Comment (IFC) (85 FR 71170).

In the 2021 CJR 3-Year extension Final Rule, we acknowledged the need for further risk adjustment to account for beneficiary-level factors that tend to impact spending in a way that is beyond the control of the provider. We introduced age bracket (less than 65 years, 65 to 74 years, 75 to 84 years, and 85 years or more), CJR HCC count (zero, one, two, three, and four or more), and dual eligibility (receiving both full Medicare and Medicaid benefits) as beneficiary-level risk adjustment factors that would be applied to each episode at reconciliation. The definition of these risk adjustment variables, and our reasoning for incorporating them into the risk adjustment methodology, is described in detail at 86 FR 23523.

The coefficients for the risk adjustment variables in the CJR extension were calculated prospectively, prior to the beginning of each performance year, using a linear regression model. As we stated at 86 FR 23524, this regression model approach would allow us to estimate the impact of each risk adjustment variable on the episode cost of an average beneficiary, based on typical spending patterns for a nationwide sample of beneficiaries with a given number of CMS–HCC conditions, within a given age bracket, and with dual eligibility or non-dual eligibility status. We used an exponential model to account for the fact that CJR episode costs are not normally distributed. A detailed description of the regression model begins at 86 FR 23524.

At reconciliation, after applying the high-cost episode cap to remove outliers, the risk adjustment coefficients for the three risk adjustment variables were applied to the episode-level target price based on the applicable episode region and MS–DRG. However, since age, CJR HCC count, and dual eligibility status are inherently included in the regional target price, since regions with beneficiaries who are older, more medically complex, and socioeconomically disadvantaged tend to have higher average episode costs, we applied a normalization factor to remove the overall impact of adjusting for age, CJR HCC count, and dual eligibility on the national average target price, as described at 86 FR 23527.

By contrast, BPCI Advanced has used a more complex risk adjustment model that includes many more risk adjustment coefficients, including both patient and provider characteristics. Categories of patient characteristics include (but are not limited to): HCCs (individual flags, interactions, and counts), recent resource use, and demographics. Provider characteristics, which are used to group hospitals into peer groups, include bed size, rural vs. urban, safety net vs. non-safety net, and whether or not the participant is a major teaching hospital. The first stage of the BPCI Advanced risk adjustment methodology uses a compound log-normal model in order to account for the substantial right skew of the distribution of episode costs. This means that it combines two log-normal distributions in order to capture costs associated with both low-cost episodes (which are the majority of episodes) and very high cost episodes (which are fewer in number but exert a strong influence on spending averages). However, participants have found the risk adjustment model difficult to interpret, particularly since is it is not widely used in other research or healthcare models.

In an effort to simplify the risk adjustment methodology for TEAM and allow participants to more easily calculate an episode level estimated target price, we propose to base our methodology on the CJR extension methodology, with a few key differences. Rather than calculate one national set of risk adjusters across all MS–DRGs for a given episode category, we propose to calculate risk adjustment coefficients at the MS–DRG/HCPCS episode type level. We considered calculating risk adjustment at the MS–DRG/HCPCS episode type/region level, but we believe that, when further subdivided into regions, the low volume of episodes for certain MS–DRG/HCPCS episode types would be insufficient to create accurate and reliable risk adjustment multipliers.

We propose to use the same age bracket risk adjustment variable (less than 65 years, 65 to less than 75 years, 75 to less than 85 years, and 85 years or more) that we use in the CJR extension, based on the participant's age on the first day of the episode, as determined through Medicare enrollment data. We also propose to use

an HCC count risk adjustment variable, but we propose to calculate it differently than the CJR HCC count risk adjustment variable. For this risk adjustment variable, which we would call the TEAM HCC count, we propose to conduct a 90-day lookback for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure. We propose to use the beneficiary's Medicare FFS claims from that 90-day lookback period to determine which HCC flags the beneficiary is assigned, and create a count of those HCC flags. This methodology would be consistent with BPCI Advanced, and would represent a more uniform way of measuring clinical complexity across beneficiaries, as opposed to using the annual HCC file that is used in CJR. It would also reduce the incentive for increased coding intensity at the time of the initiating procedure.

We propose to use an expanded risk adjustment variable that accounts for multiple potential markers of beneficiary social risk. Although it would function as a single, binary (yes=1 or no=0) variable in our risk adjustment model, the variable would represent the union of three different potential markers of beneficiary social risk. The first would be full Medicare/Medicaid dual eligibility status, which is currently used in both CJR and BPCI Advanced. We further propose to incorporate two additional elements to the beneficiary social risk adjustment variable. We propose that beneficiaries would also be assigned the value of yes=1 for the social risk adjustment variable if they either fall into a state or national Area Deprivation Index percentile beyond a certain threshold, or if they qualify for the Medicare Part D Low Income Subsidy. The beneficiary would be assigned a value of yes=1 on this single, binary social risk variable if one or more of these three indicators of social risk applied to the beneficiary. We propose to use a threshold of the 80th percentile for the national ADI and the 8th decile for the state ADI. Across other CMS Innovation Center models, as well as peer reviewed publications, and we did not find a consensus on a specific threshold that is universally used. For example, the Making Care Primary Model uses 75th percentile for the national ADI and in existing literature, some papers use a continuous measure, and some use a 75%, an 80%, or 85% cut-off.[635] [636] [637] [638] [639] Therefore, we feel that an 80% threshold is comparable to other risk adjustment methodologies. We seek comment on whether there are different thresholds for national and state ADI that we should consider. Lastly, we propose to enforce sign restrictions to avoid negative coefficients for beneficiary social risk adjustment. In other words, the adjustment to the preliminary or reconciliation target prices would only happen if the coefficient on the beneficiary social risk adjustment variable is positive. We believe enforcing sign restrictions will more accurately reflect episode spending for underserved beneficiaries who may experience access and underutilization issues. The proposed beneficiary social risk variable and our reasons for choosing each component are described in detail in section X.A.3.f of the preamble of this proposed rule.

While we are proposing a limited set of risk adjusters that is closer in number to the CJR methodology for simplicity, we considered using the same set of risk adjusters in the BPCI Advanced model because we recognize that there may be particular episode categories or MS–DRGs that would benefit from additional clinical risk adjusters. For instance, in BPCI Advanced, just over half (53%) of CABG procedures have been performed electively, with the remainder performed emergently. Some clinicians have stated their belief that CABG episodes should be priced differently based on whether they are performed electively (that is, scheduled in advance) or emergently, even when they are assigned to the same MS–DRG. They stated their belief that non-emergent procedures are generally performed on relatively healthier beneficiaries, and providers may have greater control over outcomes. Conversely, they stated that episodes following an emergency room visit on the same day or the day before tend to involve sicker patients, leading to greater clinical variability and less predictable episode spending. We are therefore requesting comment on whether TEAM's should use the BPCI Advanced episode-specific risk adjuster or if there are other potential episode-specific or MS–DRG-specific clinical risk adjusters, and how those clinical risk adjusters should be defined based on information available on the IPPS claim associated with the episode trigger.

We also considered including peer group or hospital-specific risk adjusters in TEAM. Similar to the BPCI Advanced model, we considered including peer group adjusters that would be based off of hospital characteristics, including hospital size (for example, number of hospital beds), safety net hospital status, location (for example, CBSA urban and rural indicators and census division), and if the hospital was a major teaching hospital determined by looking at the intern to bed ratio in the provider specific files.[640] We recognize including this level of risk adjustment may improve pricing accuracy for hospitals, but it introduces an additional layer of complexity to the risk adjustment model that could be challenging for TEAM participants understand when factoring in the existing risk adjustment variable and other pricing components. Since TEAM is a mandatory model, and it may capture more hospitals that have not previously participated in an episode-based payment model, we are want to create a pricing methodology that all TEAM participants, regardless of experience or resource, can understand. We seek comment on whether target prices in TEAM should include risk adjustment variables based on hospital characteristics.

Another key difference between our proposal and the current CJR risk adjustment methodology is that we propose to provide a prospective normalization factor with preliminary target prices. We propose that the prospective normalization factor would be subject to a limited adjustment at reconciliation based on the observed case mix, up to +/−5%. This would allow participants to better estimate their target prices, as it would incorporate the normalization factor prospectively, rather than only introducing the normalization factor at

[635] Kind, A., Jencks, S., Brock, J. E., Yu, M., Bartels, C. M., Ehlenbach, W. J., Greenberg, C., & Smith, M. (2014). Neighborhood socioeconomic disadvantage and 30-Day rehospitalization. Annals of Internal Medicine, 161(11), 765. *https://doi.org/10.7326/m13-2946.*

[636] Díaz, A., Lindau, S. T., Obeng-Gyasi, S., Dimick, J. B., Scott, J. W., & Ibrahim, A. M. (2023). Association of hospital quality and neighborhood deprivation with mortality after inpatient surgery among Medicare beneficiaries. JAMA Network Open, 6(1), e2253620. *https://doi.org/10.1001/jamanetworkopen.2022.53620.*

[637] Bose, S., Dun, C., Zhang, G. Q., Walsh, C., Makary, M. A., & Hicks, C. W. (2022). Medicare beneficiaries in disadvantaged neighborhoods increased telemedicine use during the COVID–19 pandemic. Health Affairs, 41(5), 635–642. *https://doi.org/10.1377/hlthaff.2021.01706.*

[638] Tung, E. L., Peek, M. E., Rivas, M., Yang, J. P., & Volerman, A. (2021). Association of neighborhood disadvantage with racial disparities in COVID–19 positivity in Chicago. Health Affairs, 40(11), 1784–1791. *https://doi.org/10.1377/hlthaff.2021.00695.*

[639] Durfey, S. N. M., Kind, A., Gutman, R., Monteiro, K., Buckingham, W. R., DuGoff, E. H., & Trivedi, A. N. (2018). Impact of risk adjustment for socioeconomic status on Medicare Advantage Plan quality Rankings. Health Affairs, 37(7), 1065–1072. *https://doi.org/10.1377/hlthaff.2017.1509.*

[640] *https://www.cms.gov/medicare/payment/prospective-payment-systems/provider-specific-data-public-use-text-format.*

reconciliation. We believe that this approach strikes a balance between predictability and protecting TEAM participants and CMS from significant shifts in patient case mix between the final baseline year and the performance year.

A goal of TEAM's risk adjustment approach is to balance simplicity with accuracy to ensure our pricing methodology reflects episode spending that accounts for provider spending trends by region and MS–DRG as well as accounting for beneficiary acuity. Our proposed risk adjustment approach relies on capturing data from Medicare claims or other sources of information that do not include patient functional assessment data. Evidence suggests that risk adjustment models may be improved when taking into account patient functional status.[641] We recognize there are existing data sets that capture patient functional status information. Specifically, the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) requires the reporting of standardized patient assessment data with regard to quality measures and standardized patient assessment data elements. The standardized patient assessment elements include functional status and are collected and reported by Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs). Since an episode encompasses post-acute care spend, the standardized patient assessment data could be incorporated into TEAM's risk adjustment methodology. However, we recognize inclusion of such data may increase the risk adjustment methodology complexity and make it challenging for TEAM participants to understand how it affects their preliminary or reconciliation target price. Therefore, we seek comment on the utility of including standardized patient assessment data in TEAM's risk adjustment methodology or whether there is other functional status data we should consider and whether standardized patient assessment data or other functional status data should be included in TEAM's risk adjustment methodology in future performance years.

To summarize, for TEAM we propose a risk adjustment methodology based on the CJR extension methodology, but with key differences that we believe would maximize target price predictability and transparency. As in CJR, we propose to use baseline data to calculate risk adjustment multipliers and hold them constant at reconciliation. We propose that participants would be provided with these risk adjustment multipliers prior to the start of the Performance Year and would be able to use them to estimate their episode-level target prices. We propose that, unlike in CJR, these risk adjustment multipliers would be calculated at the MS–DRG level, resulting in a separate set of risk adjustment multipliers for each MS–DRG episode type. We also propose to incorporate a prospective normalization factor into preliminary target prices, which would be subject to a limited adjustment at reconciliation. We seek comment on our proposals at proposed § 512.545(a–d) for risk adjusting episodes.

(5) Proposed Process for Reconciliation

This section outlines our proposals on how we intend to reconcile performance year spending for a TEAM participant's beneficiaries in episodes against the reconciliation target price in order to determine if CMS owes the TEAM participant a reconciliation payment, or if the TEAM participant owes CMS a repayment (for all Track 3 participants and beginning in performance year 2 for Track 2 hospitals). We propose to adjust the reconciliation amount for quality based on the TEAM participant's CQS, which would be constructed from their quality measure performance, to calculate the quality-adjusted reconciliation amount. We propose to apply stop-loss/stop-gain limits to the quality-adjusted reconciliation amount to determine the TEAM participant's Net Payment Reconciliation Amount (NPRA). Finally, we propose to adjust the NPRA for post-episode spending, when applicable, to determine the reconciliation payment or repayment amount.

We refer readers to section X.A.3.b.(5) of the preamble of this proposed rule for our proposed definition of related services for our proposed episodes, to section X.A.3.a.(1) of the preamble of this proposed rule for our proposed definition of performance years, and to section X.A.3.d.(3) of the preamble of this proposed rule for our proposed approach to establish preliminary target prices.

(a) Annual Reconciliation

At proposed § 512.550 we propose to conduct an annual reconciliation calculation that would compare performance year spending on episodes that ended during that PY with reconciliation target prices for those episodes to calculate a reconciliation amount for each TEAM participant. We would reconcile, on an annual basis, all episodes attributed to a TEAM participant that end in a given calendar year during the model performance period. This would be consistent with CJR and numerous other CMS value-based payment programs. We believe that one annual reconciliation accommodates the need for regular performance feedback while minimizing the administrative burden of more frequent reconciliations. Therefore, we propose to align the TEAM reconciliation approach with reconciliation in CJR, and to reconcile episodes based on performance years. We seek comment on this proposal to conduct one reconciliation for each performance year.

(b) Timing

We propose to conduct the annual reconciliation of each TEAM participant's actual episode payments against the target price(s) 6 months after the end of the performance year. This policy would be consistent with the 6 months of claims runout we allow for the CJR reconciliation for PY6–8. We believe that 6 months is sufficient time for claims runout given that an internal review of Medicare claims data found that 98.71% of IP claims had been received, and 89.96% were considered final, by 6 months after the date of service.[642] For HOPD claims, those rates were 98.10% and 95.78%, respectively. Similar rates were found for all other types of claims, including Carrier, SNF, HH, and DME, indicating that we would have a nearly complete picture of performance year spending by 6 months after the end of the performance year. For TEAM, we propose to capture claims submitted by July 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold TEAM participants responsible for repayment, as applicable, in quarters 3 or 4 of that calendar year. We seek comment on our proposal at proposed § 512.550(b) to perform reconciliation 6 months after the end of the performance year.

[641] Benefits and Challenges of Payment Adjustments Based on Beneficiaries' Ability to Perform Daily Tasks (GAO–18–588). (2018). United States Government Accountability Office. *https://www.gao.gov/assets/gao-18-588.pdf.*

[642] Medicare Claims Maturity: CCW White Paper accessed at *https://www2.ccwdata.org/web/guest/white-papers?p_l_back_url=%2Fweb%2Fguest%2Fsearch%3Fq%3Dmedicare%2Bclaims%2Bmaturity* on Jan, 26, 2024.

(c) TEAM Participants That Experience a Reorganization Event

We recognize that there may be TEAM participants that experience a reorganization event during a given performance year. At proposed § 512.505, we propose to define a reorganization event as a merger, consolidation, spin off or other restructuring that results in a new hospital entity under a given CCN. As a result of such an event, the TEAM participant may begin billing under a different CCN, or an additional entity could be incorporated into the TEAM participant's existing CCN, resulting in a new hospital entity. For instance, TEAM participant A may merge with, or be purchased by, TEAM participant B and begin billing under TEAM participant B's CCN. In this case, we propose to perform separate reconciliation calculations for TEAM participant A and TEAM participant B for those episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. We propose to reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity. We are proposing this policy in recognition that the blended entity may have different spending patterns, or a different overall patient case mix, than the two separate entities prior to the merger. In a different instance, if a TEAM participant merges into or is purchased by a non-TEAM participant and begins billing under the CCN on the non-TEAM participant, we propose to reconcile episodes for the TEAM participant where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the merger or purchase. This policy would allow for the TEAM participant to earn a reconciliation payment or owe a repayment for the episodes that occurred during the portion of the performance year that they were in the model. However, once the TEAM participant begins to bill under the non-TEAM participant's CCN, the blended entity would not be considered a TEAM participant and we would not reconcile episodes where the anchor hospitalization admission or the anchor procedure occurred on or after the effective date of the merger or purchase under the new or surviving CCN that applies to the blended entity. We seek comment on our proposal at proposed § 512.550(b)(2) for conducting reconciliations for TEAM participants that experience a reorganization event during a given performance year.

(d) Updating Preliminary Target Prices To Create Reconciliation Target Prices

As discussed in section X.A.3.d.(4) of the preamble of this proposed rule, we are proposing to apply beneficiary-level risk adjustment and a limited adjustment to the prospective normalization factor, as applicable, to increase the accuracy of our reconciliation calculations. At the time of reconciliation, we would apply these adjustments, if applicable, to the preliminary target prices we calculated and communicated to TEAM participants prior to the applicable performance year, as described in Section X.A.3.d.(3)(i) of the preamble of this proposed rule. We note that in some cases, the final target price applied to an episode in a given performance year at reconciliation will not change. In addition, in some cases the reconciliation target price will increase from the preliminary target price provided prior to the performance year, potentially benefitting TEAM participants. For instance, if the prospective normalization factor were calculated as 0.85, but the beneficiary case mix during the performance year differed from the case mix during the final year of the baseline such that the final normalization factor were calculated as 0.89, the reconciliation target price would incorporate the final normalization factor and therefore be higher than the preliminary target price.

(e) Composite Quality Score

(i) Overview

Incorporating quality performance into the model payment structure is an essential component of TEAM, just as it is for the CJR model (80 FR 73370) and BPCI Advanced. Section X.A.3.c of the preamble of this proposed rule discusses the specific measures for which we propose that TEAM participants would be held accountable. In addition to Quality Payment Program requirements to tie quality performance to payment for Advanced APMs, we believe it is important for TEAM to link the opportunity to earn a reconciliation payment with performance on quality measures to place greater emphasis on beneficiary quality of care and patient-centered care.

As discussed in section X.A.3.d.(5)(g) of the preamble of this proposed rule, which outlines the proposed process for incorporating quality into the reconciliation calculation, for each TEAM participant, we propose to calculate the difference between the TEAM participant's performance year spending and their reconciliation target price at reconciliation, identified as the reconciliation amount. We propose that the reconciliation amount would then be adjusted based on the TEAM participant's quality performance. We propose to use the quality measures discussed in section X.A.3.c of the preamble of this proposed rule to calculate a Composite Quality Score, in a similar manner to what we have implemented for many CMS models and initiatives, including CJR and BPCI Advanced. The Composite Quality Score (CQS) methodology would allow performance on each required TEAM quality measure to be meaningfully valued in the TEAM pay- for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the TEAM participant.

For TEAM, the actual level of quality performance achieved will be the most important factor in calculating the CQS to reward those TEAM participants furnishing high quality care to TEAM beneficiaries. Like the CJR model, TEAM would include a wide range of participants with varying levels of experience with value-based care and different current levels of quality performance. Other CMS programs, also capture a wide range of participants and include quality performance methodologies that may directly affect the participant's financial performance. We note that the Shared Savings Program utilizes similar features as the proposed TEAM CQS methodology, such as benchmarking quality performance, calculating scores for each measure and constructing an overall score (see 42 CFR 425.502). Additionally, the Hospital VBP Program and the HAC Reduction Program also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (42 CFR 412.165 and 42 CFR 412.172). Despite the small number of quality measures proposed for TEAM, the measures represent both clinical outcomes and patient experience, and each would carry substantial value in the TEAM composite quality score.

Although performance on each measure would be valued in the TEAM composite quality score methodology, it is the TEAM participant's overall quality performance that would be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under TEAM. The TEAM composite score methodology also provides a framework for incorporating additional

measures of meaningful outcomes for episodes in the future. The TEAM composite score methodology would provide the potential for financial reward for TEAM participants that reach an overall acceptable quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of episodes. We seek comment on our proposal to use a composite quality score in the pay-for-performance methodologies of TEAM.

(ii) Determining Composite Quality Score

The CQS is one component of the reconciliation process and we propose that it would be calculated based on the TEAM participant's performance on the quality measures proposed for the model. One of the primary purposes of the CQS is to create a comparative assessment for performance across episode categories and TEAM participants. Since not all quality measures apply to all episode categories, quality measures that apply to more episode categories will be volume-weighted more heavily in the CQS.

As indicated in section X.A.3.c.(3) of the preamble of this proposed rule, the proposed TEAM quality measures would be collected from the CMS Hospital IQR Program and the HAC Reduction Program. The proposed TEAM quality measures collected from the Hospital IQR Program and HAC Reduction Program would have raw quality measure scores, however, these raw quality measure scores may be in different measurement units making it difficult to make comparisons. Therefore, raw quality measure scores must be manipulated in order to produce a CQS. Similar to the BPCI Advanced model, for each TEAM performance year we propose for each quality measure to convert raw quality measure scores into scaled quality measure scores by comparing the raw quality measure score to the distribution of raw quality measure score percentiles among the national cohort of hospitals, which would consist of TEAM participants and hospitals not participating in TEAM, in the CQS baseline period, so that each measure has a scaled quality measure score between 0 and 100 for each episode category. For example, if a TEAM participant's raw quality measure score of 71% in PY 1 is equivalent to the 60th percentile during the CQS baseline period, their scaled quality measure score for that measure will be 60 in the performance year. We recognize there may be instances where the raw quality score may fall between percentiles or may be higher or lower than the raw quality scores in the CQS baseline period. Therefore, we propose if the raw quality measure score could belong to either of two percentiles in the CQS baseline period, then we would assign the higher percentile. Further we would assign a scaled score of 100 if the TEAM participant has a raw quality measure score greater than the maximum of the raw quality measure scores in the CQS baseline period and assign a scaled quality measure score of zero if the TEAM participant has a raw quality score less than the minimum of the raw scores in the CQS baseline period. Lastly, we would not assign a scaled quality measure score if the TEAM participant has no raw quality measure score.

We propose the CQS baseline period to be calendar year 2025 for the duration of TEAM. We believe using calendar year 2025 as the CQS baseline period is similar with other CMS Innovation Center models, including the BPCI Advanced model, where the baseline period was established before the incentives of the model were in place in order to assess quality improvement. We considered using a contemporaneous CQS baseline period, where the CQS baseline period would be the same as the performance year for each performance year, but we believe that may increase CQS calculation complexity and may create challenges for TEAM participants to implement meaningful quality improvement efforts. Lastly, we also considered a rolling CQS baseline period, where the CQS baseline period would move forward by one year each performance year, but similar to a contemporaneous CQS baseline period, we believe the simplicity of have a fixed CQS baseline period will be easier for TEAM participants to understand the CQS calculation methodology. However, as indicated in section X.A.3.b.(1) of the preamble of this proposed rule, we recognize the potential for additional episodes added to TEAM in future performance years, which may result in different quality measures being used in the CQS calculation. If new episodes categories or quality measures are introduced to TEAM, we would reassess the CQS baseline period and implement any changes in future notice and comment rulemaking.

Prior to calculating the CQS, we propose volume weighting the quality measures based on the volume of episodes for a TEAM participant. Specifically, a normalized weight would be calculated by dividing the TEAM participant's volume of episodes for a given quality measure by the total volume of all the TEAM participant's episodes. This calculation would be applied to all quality measures for the TEAM participant (see Table X.A.–06). We believe it is important to volume weight the quality measures so that more weight is given to the quality measures that apply to more episode categories.

TABLE X.A.-06 – EXAMPLE QUALITY MEASURE NORMALIZED WEIGHTS CALCULATION

Quality Measure	Volume of Episodes	Normalized Weight
Hybrid Hospital-Wide Readmission (CMIT ID 356)	650	0.38
CMS Patient Safety and Adverse Events Composite (CMIT ID 135)	650	0.38
Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (CMIT ID 1618)	400	0.24
	1,700	1.00

We would then take the quality measures normalized weights and combine it with the scaled quality measure scores to determine the weighted scaled score. Specifically, we propose to calculate a weighted average by multiplying each quality measure's scaled quality measure score by its normalized weight to create weighted scaled scores for a TEAM participant. The weighted scaled scores would then be added together to construct the CQS

for the TEAM participant (see Table X.A.–07)

TABLE X.A.-07 – EXAMPLE WEIGHTED SCALED SCORE AND CQS CACLULATION

Quality Measure	Scaled Quality Measure Score	Normalized Weight	Weighted Scaled Score
Hybrid Hospital-Wide Readmission (CMIT ID 356)	60	0.38	22.8
CMS Patient Safety and Adverse Events Composite (CMIT ID 135)	50	0.38	19
Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (CMIT ID 1618)	40	0.24	9.6
Composite Quality Score			51.4

Lastly, although the required set of quality measures proposed for TEAM are ones currently being reported through the Hospital IQR Program and HAC Reduction Program, we recognize that CMS may, in future regulations, remove current measures or require different measures for hospitals to report in the Hospital IQR Program and HAC Reduction Program. Therefore, CMS may propose changes to the TEAM measures and the methodology for constructing the composite quality score through future notice and comment rulemaking. We seek comment on our proposed methodology to calculate the TEAM composite quality score.

(f) Calculating the Reconciliation Payment Amount or Repayment Amount

After the completion of a performance year, we propose to retrospectively calculate a TEAM participant's actual episode performance based on the episode definition. We note that episode spending would be subject to proration for services that extend beyond the episode (as described in section X.A.3.d.(3)(c) of the preamble of this proposed rule). We propose to cap performance year spending at the high-cost outlier cap as described in section X.A.3.d.(3)(e) of the preamble of this proposed rule. We propose to apply the high-cost outlier cap to episodes in the performance year similarly to how we propose to apply it to baseline episodes, using the 99th percentile for each MS–DRG/HCPCS episode type and region as the maximum. Any performance year episode spending amount above the high cost outlier cap would be set to the amount of the high cost outlier cap. We then propose to compare each TEAM participant's performance year spending to its reconciliation target prices. Specifically, we propose to define the reconciliation amount as the dollar amount representing the difference between the reconciliation target price and performance year spending, prior to adjustments for quality, stop-gain/stop-loss limits, and post-episode spending. We note that, as discussed in section X.A.3.d.(3) of the preamble of this proposed rule, a TEAM participant would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG/HCPCS episode type and the performance year when the episode was initiated. We propose to determine the applicable reconciliation target price for each episode using the aforementioned criteria, and calculate the difference between each TEAM participant's performance year spending and its aggregated reconciliation target price for all episodes in the performance year, resulting in the reconciliation amount. Specifically, we propose to define the reconciliation amount as the dollar amount representing the difference between the reconciliation target price and performance year spending, prior to adjustments for quality, stop-gain/stop-loss limits, and post-episode spending. We propose to adjust the reconciliation amount for quality performance as discussed in section X.A.3.d.(5)(e) of the preamble of this proposed rule to determine the quality-adjusted reconciliation amount. We then propose to apply the stop-loss and stop-gain limits to the quality-adjusted reconciliation amount, as discussed in section X.A.3.d.(5)(f) of the preamble of this proposed rule, creating the Net Payment Reconciliation Amount (NPRA). Finally, we propose to combine the NPRA with the results of the post-episode payment calculation (as discussed in section X.A.3.d.(5)(g) of the preamble of this proposed rule), to create the reconciliation payment amount or repayment amount. We seek comment on our proposal at proposed § 512.550(c-g) for calculating the reconciliation payment amount or repayment amount.

We do not propose to include any TEAM reconciliation payments or repayments to Medicare under this model for a given performance year in the reconciliation amount for a subsequent performance year. We want to incentivize providers to provide high quality and efficient care in all years of the model. If reconciliation payments for a performance year are counted as performance year spending in a subsequent performance year, a hospital would experience higher performance year spending in the subsequent performance year as a consequence of providing high quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we propose to not have the reconciliation amount for a given performance year be impacted by TEAM Medicare repayments or reconciliation payments made in a prior performance year. We seek comment on our proposal not to include TEAM reconciliation payments or repayments in performance year spending.

(g) Incorporating the Composite Quality Score Into the Reconciliation Amount

As indicated in section X.A.3.c of the preamble of this proposed rule, the TEAM quality measure assessment is a pay-for-performance methodology aimed to incentivize and reward cost savings in relation to the quality of episode care provided by the TEAM participant. Similar to the BPCI Advanced model, we propose that a TEAM participant's quality performance would be linked to payment by translating the CQS into a CQS adjustment percentage and applying the CQS adjustment percentage to any positive or negative reconciliation amount. Specifically, for Track 1 TEAM

participants we propose that the CQS adjustment percentage would adjust a positive reconciliation amount up to 10%, and because Track 1 does not have downside risk, there would be no CQS adjustment percentage for negative reconciliation amounts. In the event a TEAM participant in Track 1 would have earned a negative reconciliation amount, their CQS would still be reported in their reconciliation report so that they may use this information to improve their quality measure performance in the next performance year. For Track 2 we propose that the CQS adjustment percentage would adjust a positive reconciliation amount up to 10% and a negative reconciliation amount up to 15%. In other words, the CQS adjustment percent would not adjust the positive reconciliation amount down by more than 10%, nor would it adjust the negative reconciliation amount up (meaning more towards a positive amount) by more than 15%. For Track 3 TEAM participants, we propose that the CQS adjustment percentage would adjust a positive reconciliation amount up to 10% and a negative reconciliation amount up to 10%. We would determine the CQS adjustment percentage using the following proposed formulas in Table X.A.–08.

TABLE X.A.-08 – TEAM PROPOSED CQS ADJUSTMENT PERCENTAGE FORMULAS

Track	Reconciliation Amount	CQS Adjustment Percentage Formula
Track 1	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 2	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 2	Negative Reconciliation Amount	CQS adjustment percentage = (15% * (CQS/100))
Track 3	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 3	Negative Reconciliation Amount	CQS adjustment percentage = (10% * (CQS/100))

The CQS adjustment percentage would be multiplied with the TEAM participant's positive or negative reconciliation amount to produce the CQS adjustment amount. The CQS adjustment amount would then be subtracted from the positive or negative reconciliation amount to create the quality-adjusted reconciliation amount. We propose to define the quality-adjusted reconciliation amount as the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality, but prior to application of stop-gain/stop-loss limits and the post-episode spending adjustment, as described in sections X.A.3.d.(5)(h). and X.A.3.d.(5)(i). of the preamble of this proposed rule. Since Track 2 participation after is limited to TEAM participants who may care for a higher proportion of underserved TEAM beneficiaries, we believe an asymmetric application of the CQS adjustment percentage for Track 2 TEAM participants may help to mitigate some the negative financial burden that may be associated with caring for underserved beneficiaries who tend to be higher cost and have worse health outcomes. Table X.A.–09 illustrates TEAM's proposed methodology of incorporating CQS into payment using the different CQS adjustment percentage scenarios using rounded values.

TABLE X.A.-09 – EXAMPLE OF PROPOSED CQS APPLICATION

Participant Track	Reconciliation Amount	CQS	CQS Adjustment Percentage	CQS Adjustment Amount	Quality-Adjusted Reconciliation Amount
Track 1	$24,000	72	2.8%	$672	$23,328
Track 1	-$19,500	88	0.0%	$0	$0.00
Track 2	$10,000	45	5.5%	$550	$9,450
Track 2	-$7,500	66	9.9%	$743	-$6,757
Track 3	$38,000	51	4.9%	$1,862	$36,138
Track 3	-$26,500	93	9.3%	$2,465	-$24,035

We considered an asymmetric application of the CQS adjustment percentage for TEAM participants in Track 3, but we believe the proposed symmetric application is appropriate to balance the amount of financial risk associated with quality performance since Track 3 is meant to have higher risks and rewards. Further, we also considered different CQS adjustment percentages for TEAM participants in all tracks including 20%, 25%, 33% and 50% but felt that these percentages may be too high given TEAM participants will have varying levels of experience with value-based care and a pay-for-performance methodology. We also considered lower CQS adjustment percentages for TEAM participants in all tracks including 1%, 3%, and 5%, but we believe these percentages would be too low and minimize the importance of quality improvement and thus would not incentivize TEAM participants to strive for quality of care improvements.

We also considered other approaches to tying TEAM quality measure performance to payment, including how the CJR Model applied their CQS methodology to adjust the discount factor. However, we believe the TEAM's proposed approach creates a greater incentive to improve quality measure performance because a TEAM participant must achieve of a CQS of 100 in order to receive the maximum quality-adjusted reconciliation amount. While this may be perceived as setting

a high standard, it is consistent with the approach we have taken in BPCI Advanced and also emphasizes the importance of beneficiary quality of care. Lastly, we considered applying a CQS threshold in order to be eligible to receive a reconciliation payment in TEAM. A similar approach was used in the CJR model where a participant hospital had to achieve a minimum CQS in order to receive a reconciliation payment, however, a level of quality performance that was below acceptable would not affect participant hospitals' repayment responsibility. We believe TEAMs proposed pay-for-performance methodology does not need a CQS threshold since poor quality performance in TEAM would negatively affect any positive or negative reconciliation amount.

We seek comment on TEAM's proposed methodology at proposed § 512.550(d) to calculate and apply the CQS. We also seek comment on our proposed definition of quality-adjusted reconciliation amount at § 512.505.

(h) Limitations on NPRA

In CJR and BPCI Advanced, we included both stop-loss and stop-gain limits on the total amount that a participant could owe to CMS as a repayment or receive from CMS as a reconciliation payment. For CJR, this policy and its justification is described in the 2015 CJR Final Rule at 80 FR 73398. For both CJR and BPCI Advanced, these limits were applied as a percentage of a participant's total aggregate target price at reconciliation. Stop-loss and stop-gain limits gradually increased over the first few years of the CJR model, reaching a maximum of 20% for most hospitals for performance years 4–8, while the BPCI Advanced model has maintained 20% limits every model year for all participants.

As with CJR, we propose to phase in risk in TEAM. We propose that Track 1 TEAM participants would not be subject to downside risk in performance year 1. We also propose a stop-gain limit of 10% for Track 1 TEAM participants in performance year 1. We propose that TEAM participants in Track 2 would be subject to downside and upside risk with a symmetric stop-gain and stop-loss limits of 10% for PY 2–5. We believe a 10% stop-gain and stop-loss limit of 10% is appropriate for Track 2 participants who can gain value-based care experience but have less financial risk. However, since Track 3 would be designed for TEAM participants with prior experience in value-based care or those who are prepared to accept greater financial risk in the first year of TEAM, we propose that TEAM participants that opt into Track 3 of the model would be subject to both upside and downside risk, with symmetric stop-gain and stop-loss limits of 20% for all performance years. The greater level of downside risk in Track 3 would therefore be balanced by higher stop-gain limits for Track 3 compared to Track 1 or Track 2, which we propose to continue for all performance years.

We considered, but are not proposing, higher and lower stop-gain and stop-loss limits for Track 3, including 25%, 15%, and 10% but we believe maintaining consistency with 20% stop-gain and stop-loss limits of previous episode-based payment models provides the appropriate balance of financial risk and reward to promote spending reductions with reasonable risk thresholds. We also considered lower stop-gain and stop-loss limits for Track 2, including 5%, 3% and 1% limits, or asymmetric limits, such as 10% stop-gain and 5% stop-loss limits or 5% stop-gain and 3% or 1% stop-loss. We also considered, but are not proposing, lower and asymmetric limits for certain TEAM participants. For example, we considered a 10% or 5% stop-gain paired with a 3% or 1% stop-loss for TEAM participants who meet the criteria of a safety net hospitals. Since TEAM offers a one-year glide path where all TEAM participants could elect to participate in Track 1 with no downside risk for PY1, we don't believe lower or asymmetric limits would be necessary for Track 2. By PY2 when Track 2 is available for certain TEAM participants, they should have sufficient infrastructure in place to assume two-sided risk while having less financial risk compared to Track 3. We seek comment on these alternative proposals for stop-gain and stop-loss limits and whether there are other mechanisms we should consider to help limit a TEAM participant's financial risk in the model.

We also propose to apply stop-loss and stop-gain limits after application of the CQS which would result in the NPRA. We propose to define NPRA as the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality and stop-gain/stop-loss limits, but prior to the post-episode spending adjustment, which is described in section X.A.3.d.(5)(g) of the preamble of this proposed rule. We believe applying the stop-loss and stop-gain limits after the CQS is appropriate because it limits the financial risk associated with episode spending and quality performance, which is similar to how the BPCI Advanced model and CJR model apply stop-loss and stop-gain limits.

We seek comment on our proposal at proposed § 512.550(c)(vi) for differential stop-gain and stop-loss limits for TEAM participants by Track and Performance Year. We also seek comment on our NPRA definition at proposed § 512.505.

(i) Participant Responsibility for Increased Post-Episode Payments

While the proposed episodes would extend 30 days post-discharge from the anchor hospitalization or post-procedure (for outpatient episodes), some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. We do not believe this would be likely, but in order to identify and address such inappropriate shifting of care, we propose to calculate for each performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed episode definition (section X.A.3.b.(5) of the preamble of this proposed rule). Because we base the proposed episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–10–CM diagnosis codes for Part B services as discussed in section X.A.3.b.(5)(a) of the preamble of this proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during episodes, there is some potential for hospitals to inappropriately withhold or delay a variety of types of services until the episode concludes regardless of whether the service is included in the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a hospital engaged in shifting of medically necessary services outside the episode for potential financial benefit may be unlikely to clearly distinguish whether the services were related to the episode or not.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section X.A.3.d.(3)(c) of this proposed rule. Specifically, at proposed

§ 512.550(f) we propose to identify whether the average 30-day post-episode spending for a TEAM participant in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all TEAM regional hospitals in the same region as the TEAM participant. We proposed that beginning with PY1 for Track 3 TEAM participants, and PY2 for Track 2 TEAM participants, if the TEAM participant's average post-episode spending exceeds this threshold, the amount above the threshold would be subtracted from the reconciliation amount or added to the repayment amount for that performance year. The amount above the threshold would not be subject to the stop-loss limits proposed elsewhere in the proposed rule. We seek comment on this proposal at proposed § 512.550(f) to make TEAM participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

(j) Reconciliation Payments and Repayments

For the performance year 1 reconciliation process for Track 1 TEAM participants, we would combine a TEAM participant's NPRA and post-episode spending amount, as described previously in this section, and if positive, the TEAM participant would receive the amount as a one-time lump sum reconciliation payment from Medicare. If negative, the TEAM participant would not be responsible for repayment to Medicare, consistent with our proposal for a 1-year glide path to phase in greater financial responsibility in the model. For TEAM participants in Track 3 for PY 1, and Track 2 or Track 3 for PYs 2–5, if the amount is positive, the TEAM participant would receive the amount as a one-time lump sum reconciliation payment from Medicare. If the amount is negative, Medicare would hold the TEAM participant responsible for a one-time lump sum repayment. CMS would collect the one-time lump sum repayment in a manner that is consistent with all relevant federal debt collection laws and regulations.

We want participants to succeed in TEAM by providing high quality care to TEAM beneficiaries and reducing episode spending, but we understand there may be instances when a TEAM participant does not meet performance metrics and owes a repayment amount. We acknowledge paying back Medicare in a lump sum for a repayment amount may introduce financial hardship for some TEAM participants, especially those who may be new to value-based care with downside risk or those who have fewer financial resources. In some CMS Innovation Center models, certain participants are required to have financial guarantees, which act as a reinsurance policy for CMS if the participant is unable to pay back debts owed as a result of their performance in the model. For example, the BPCI Advanced model requires certain participants to have secondary repayment sources, generally in the form of a letter of credit or escrow agreement, that can be drawn upon if the participant is unable or fails to pay their repayment amount. Yet, financial guarantees require upfront capital and must be replenished in a timely manner for potential use in future debts. Further, financial guarantees generally need to be established before the model starts, thus before the TEAM participant would be eligible to use any TEAM payment amounts to fund the financial guarantee.

We do not believe financial guarantees would be appropriate for TEAM given the aforementioned concerns but recognize that providing some process to prolong recovery of a repayment amount may be needed to mitigate potential financial hardships. Existing Medicare policy allows the recovery of Medicare debt, defined as recoupment in 42 CFR 405.370, and non-Medicare debt, defined as offset in 42 CFR 405.370, by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. To leverage the existing Medicare policy to recover debts in TEAM, we considered whether the reduction of present or future Medicare payments should be a dollar amount reduction, for example a $100 reduction of all Medicare payments, or a percentage reduction applied to all Medicare payments, for example a 2% reduction to Medicare payments. A dollar amount reduction may be simpler to calculate while translating a debt to a percentage reduction may be more complex to calculate. We also considered whether the reduction of present or future Medicare payments should only be associated with a TEAM participant's Medicare Part A payments for the corresponding episode categories tested in TEAM or for all of a TEAM participant's Medicare Part A payments. Limiting the Medicare payment reduction to only corresponding episode categories tested in TEAM may draw out the length of time for debt recovery, but it may ease TEAM participant bookkeeping when accounting for TEAM financial performance. Conversely, reduction of Medicare payments for all of a TEAM participant's Medicare Part A payments may reduce the length of time for debt recovery, but it may be more challenging to identify and track TEAM participant financial performance.

We are not proposing to require financial guarantees or change existing Medicare recoupment or offsetting policies, but we are seeking comment on whether we should consider these options further or if there are other ways to reduce financial hardship for TEAM participants that owe a repayment amount. We also seek comment on whether we should consider a Medicare payment policy waiver to reduce financial hardship, what the waiver would waive, and if the waiver is necessary to avoid undue burden on TEAM participants.

We also considered an alternative approach to making reconciliation payments and collecting repayments from TEAM participants. Under this alternative approach, in lieu of making a lump sum payment to TEAM participants, or collecting a repayment amount from TEAM participants, we would instead make a percentage adjustment to future FFS claims for TEAM participants. The magnitude of the adjustments would be intended to approximate the same dollar amount that would be paid or recouped via a reconciliation process; adjustments would be made in the form of a multiplier on claims for the anchor procedures for the episodes included in TEAM. For example, we would make adjustments to IPPS claims containing the MS–DRGs included in the model, and the amounts of the adjustments for each TEAM participant over the course of a year would, in aggregate, be intended to approximately equal the dollar amount that would have otherwise been paid via a reconciliation payment (or recouped via a repayment amount). The alternative approach would look similar to the operational payment mechanisms used in other Medicare programs and initiatives such as the Hospital Value-Based Purchasing Program, the SNF Value-Based Purchasing Program, the Expanded Home Health Value-Based Purchasing Model, and the Hospital Readmissions Reduction Program. We considered a value-based purchasing payment approach because we believe it has the potential to be less operationally cumbersome than making separate reconciliation payments if TEAM is expanded nationally in the future. We

also believe that a value-based purchasing payment approach that adjusts future FFS claims up or down would provide financial stability for TEAM participants, because they would receive notice of their adjustment amounts ahead of the year in which those adjustments would apply, and TEAM participants that would otherwise owe a repayment amount could effectively pay that debt over time automatically via claims adjustments, versus writing a check to CMS.

A value-based purchasing approach for TEAM would not be without challenges, however. First, preliminary modeling indicates that payment adjustment percentages for the proposed episodes may need to be relatively large in order to approximate the same dollar amount that would otherwise be paid out via a reconciliation payment, or paid to CMS via a repayment amount. Although the adjustment percentages would be limited to a subset of FFS claims for a given TEAM participant, we believe we must be cautious that particularly for some providers, a negative adjustment to FFS claims could represent a financial hardship. Second, we considered whether claims adjustments should be made to only IPPS claims (for the MS–DRGs that trigger an anchor procedure/hospitalization for an episode), or also to OPPS claims, given that we are proposing to include episodes that initiate in the outpatient setting in TEAM for certain episode categories. Making adjustments to both IPPS and OPPS claims would add complexity, particularly since the IPPS payment updates are made on a fiscal year schedule, while the OPPS updates payments on a calendar year cycle. We seek comment on whether, for TEAM or other future initiatives that may consider a similar value-based purchasing approach, we should make adjustments to IPPS claims only or also OPPS claims that trigger model episodes.

We seek comment on our proposal making reconciliation payments to, and collecting repayment amounts from, TEAM participant as a one-time, lump sum payment, as well as the alternative considered to implement a value-based purchasing approach where we make payment adjustments to future FFS claims in lieu of lump sum payments or repayments.

(6) Proposed Appeals Process

(a) First Level Appeal Process

At proposed § 512.560, we propose the following first level appeal process for TEAM participants to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the TEAM participant's reconciliation amount or repayment amount as reflected on a TEAM reconciliation report; the calculation of NPRA; and the calculation of the CQS. We propose that TEAM participants would review their TEAM reconciliation report and be required to provide a notice of calculation error that must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, we propose that the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. We propose that if CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the TEAM participant. We propose that if a TEAM participant does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the TEAM participant would be precluded from later contesting any element of the TEAM reconciliation report for that performance year.

At proposed § 512.560(b) we propose an exception to the appeals process. We propose that if a TEAM participant contests a matter that does not involve an issue contained in, or a calculation that contributes to, a TEAM reconciliation report, a notice of calculation error is not required. A notice of calculation error form would not be an appropriate format for addressing issues other than calculation errors, given that it is tailored specifically to calculation errors. In these instances, we propose that if CMS does not receive a request for reconsideration from the TEAM participant within 10 calendar days of the notice of the initial reconciliation, the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination. We note that this proposed exception does not apply to the limitations on review in § 512.594.

We solicit comment on our proposal for the first level appeals process.

(b) Reconsideration Review Process

At proposed § 512.561, we propose a reconsideration process that is based on processes implemented under current models being tested by the CMS Innovation Center. The process would enable TEAM participants to contest determinations made by CMS. We propose at to waive section 1869 of the Act, which governs determinations and appeals in Medicare and instead we propose to codify a reconsideration process for TEAM participants to utilize. We propose at § 512.561(a) that only TEAM participants may utilize the dispute resolution process. We believe establishing a reconsideration process is necessary to give TEAM participants a means to dispute certain determinations made by CMS.

This proposed reconsideration review process would be utilized in the case that a determination has been made and the TEAM participant disagrees with that determination. Part 512 subpart E would include specific details about when a determination is final and may be disputed through the reconsideration review processes.

We propose at § 512.561(b) that TEAM participants may request reconsideration of a determination made by CMS, only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or this subpart. We propose at § 512.561(b)(1)(i) that a request for review of those final determinations made by CMS that are not precluded from administrative or judicial review would be submitted to a CMS reconsideration official. The CMS reconsideration official would be authorized to receive such requests and would not have been involved in the initial determination or, if applicable, the notice of calculation error process. We propose at § 512.561(b)(1)(ii) that the reconsideration review request would be required to include a copy of CMS's initial determination, contain a detailed written explanation of the basis for the dispute, and at § 512.561(b)(1)(iii) that the request would have to be made within 30 days of the date of CMS's initial determination via email addressed to an address specified by CMS. At § 512.561(b)(2), we propose that requests that do not meet the requirements of paragraphs (b)(1) are denied.

We propose that the reconsideration official would send a written acknowledgement to CMS and to the TEAM participant requesting reconsideration within 10 business days of receiving the reconsideration request. The acknowledgement would set forth the review procedures and a schedule that permits each party an opportunity to submit documentation in support of their position for consideration by the reconsideration official.

We propose at § 512.561(b)(1)(i)(B), that, to access the reconsideration process for a determination concerning a TEAM payment, the TEAM participant

would be required to satisfy the notice of calculation error requirements specified in section X.A.3.d.(6)(a) of the preamble of this proposed rule before submitting a reconsideration request under this process. In the event that the model participant fails to timely submit an error notice with respect to a TEAM payment, we propose that the reconsideration review process would not be available to the TEAM participant with regard to that payment.

We propose to codify standards for the reconsideration at § 512.561(c). First, during the course of the reconsideration, both CMS and the party requesting the reconsideration must continue to fulfill all responsibilities and obligations during the course of any dispute arising under TEAM. Second, the reconsideration would consist of a review of documentation timely submitted to the reconsideration official and in accordance with the standards specified by the reconsideration official in the acknowledgement at § 512.561(b)(3). Finally, we propose that the burden of proof would be on the TEAM participant to prove to the reconsideration official, by a standard of clear and convincing evidence, that the determination made by CMS was inconsistent with the terms of TEAM.

We propose to codify at § 512.561(d) that the reconsideration determination would be an on-the-record review. By this, we mean a review that would be conducted by a CMS reconsideration official who is a designee of CMS who is authorized to receive such requests under proposed § 512.561(b)(1)(i), of the position papers and supporting documentation that are timely submitted and meet the standards of submission under proposed § 512.561(b)(1) as well as any documents and data timely submitted to CMS by the TEAM participant in the required format before CMS made the initial determination. Under the proposed § 512.561(d)(2), the reconsideration official would issue to CMS and the TEAM participant a written reconsideration determination. Absent unusual circumstances in which the reconsideration official would reserve the right to an extension upon written notice to the TEAM participant, the reconsideration determination would be issued within 60 days of CMS's receipt of the timely filed position papers and supporting documentation. Under proposed § 512.561(d)(3), the determination made by the CMS reconsideration official would be final and binding 30 days after its issuance, unless the TEAM participant or CMS were to timely request review of the reconsideration determination by the CMS Administrator in accordance with § 512.5610(e)(1) and (2).

(c) CMS Administrator Review Process

We propose to codify at § 512.561(e) a process for the CMS Administrator to review reconsideration determinations made under proposed§ 512.561(d). We propose that either the TEAM participant or CMS may request that the CMS Administrator review the reconsideration determination made by the reconsideration official. Under proposed § 512.561(e)(1), the request to the CMS Administrator would have to be made via email, within 30 days of the reconsideration determination, to an email address specified by CMS. The request would have to include a copy of the reconsideration determination, as well as a detailed written explanation of why the model participant or CMS disagrees with the reconsideration determination. Under proposed § 512.561(e)(4), promptly after receiving the request for review, the CMS Administrator would send the parties an acknowledgement of receipt that outlines whether the request for review was granted or denied and, should the request for review be granted, the review procedures and a schedule that would permit both CMS and the TEAM participant an opportunity to submit a brief in support of their positions for consideration by the CMS Administrator. Should the request for review be denied, under proposed § 512.561(e)(5), the reconsideration determination would be final and binding as of the date of denial of the request for review by the CMS Administrator. Under proposed § 512.561(e)(6), should the request for review by the CMS Administrator be granted, the record for review would consist solely of timely submitted briefs and evidence contained in the record before the reconsideration official and evidence as set forth in the documents and data described in proposed § 512.561(d)(1)(ii); the CMS Administrator would not consider evidence other than information set forth in the documents and data described in proposed § 512.561(d)(1)(ii). The CMS Administrator would review the record and issue to CMS and the TEAM participant a written determination that would be final and binding as of the date the written determination was sent.

We invite public comment on the proposed reconsideration review process for TEAM.

e. Model Overlap

(1) Background

When determining the best strategy for addressing model overlap, we recognize we need to consider how to promote meaningful collaboration between providers and TEAM participants. In prior models, overlap policies were intended to be simple by avoiding duplicative incentive payments or giving precedence to a single accountable entity. However, what resulted were confusing methodologies or misaligned incentives which were difficult to navigate. Participants from prior models have also cited confusion with identifying to which model(s) a beneficiary may be aligned or attributed.

In earlier episode-based payment models, such as CJR (in certain circumstances) and BPCI, CMS addressed overlap by implementing a complex calculation and recouping a portion of the pricing discount for providers also participating in certain ACO initiatives. The recoupment was intended to prevent duplicate incentive payments for the same beneficiary's care; however, some participants perceived the resulting recoupment as a financial loss, discouraging providers from participating in both initiatives.

(2) Previous Episode-Based Model Overlap Policies

To avoid complexity, the CJR and BPCI Advanced models exclude beneficiaries aligned or assigned to certain ACOs, and these beneficiaries will not trigger a clinical episode.[643] While this exclusionary approach creates a clean demarcation of who is accountable for a beneficiary's care, it also limits the number of providers in accountable care relationships and becomes less tenable as we work towards the goal of increased accountability. Additionally, participants may be informed of beneficiary ACO alignment or assignment after the potential episode has been initiated and the expending of resources on unattributed beneficiaries. This concern highlights the opportunity to incentivize coordinated care, expand care redesign efforts to more patients, and strengthen APM participation.

Even passive avoidance of duplicated payments has its drawbacks such as lack

[643] Currently, the BPCI Advanced model does not allow overlap with the ACO Realizing Equity, Access, and Community Health (ACO REACH) model, the Vermont Medicare ACO Initiative, and the Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices (KCC) Model. The CJR model does not allow overlap with the ENHANCED Track of the Medicare Shared Savings Program.

of incentive to coordinate care. For example, the CJR and BPCI Advanced models allow overlap with the Medicare Shared Savings Program without a financial recoupment.[644] [645] However, this policy does not encourage behavior change to ensure a smooth transition back to population-based providers.

(3) Beneficiary Overlap

We acknowledge that there may be circumstances where a Medicare beneficiary in an episode may also be assigned to an ACO, advanced primary care model, or other model or initiative being implemented through the CMS Innovation Center or otherwise through CMS. For the purposes of this proposed rule, ''total cost of care'' models or programs refer to models or programs in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. We use the term ''shared savings'' in this proposed rule to refer to models or programs in which the payment structure includes a calculation of savings (that is, the difference between FFS amounts and program or model benchmark) and CMS and the model or program participant each retain a particular percentage of that savings. We note that there exists the possibility for overlap between episode-based payment model and shared savings models or programs such as Shared Savings Program, specialty care models such as the Enhancing Oncology Model (EOM), advanced primary care models such as Making Care Primary (MCP), state-based models such as the All-Payer Health Equity Approaches and Development model (AHEAD), or other CMS Innovation Center payment models that incorporate per-beneficiary-per-month (PBPM) fees or other payment structures. In addition to the Shared Savings Program, there are other ACO and CMS Innovation Center models that make or will make, once implemented, providers accountable for total cost of care over a period of time (for example, 6 to 12 months). Some of these are shared savings models (or programs, in the case of the Shared Savings Program), while others are not shared savings but hold participating providers accountable for the total cost of care during a defined episode. Each of these payment models or programs holds providers accountable for the total cost of care over the course of an extended period or episode by applying various payment methodologies. We believe it is important to simultaneously allow beneficiaries to participate in broader population-based and other total cost of care models, as well as episode payment models that target a specific episode with a shorter duration, such as TEAM. Allowing beneficiaries to receive care under both types of models may maximize the potential benefits to the Medicare Trust Funds and participating providers and suppliers, as well as beneficiaries. Research suggests that shared beneficiaries in episode-based payment models and ACOs can lead to lower post-acute care spending and reduced readmissions.[646] Beneficiaries stand to benefit from care redesign that may lead to improved quality for episodes even while also receiving care under these broader models, while entities that participate in other models and programs that assess total cost of care stand to benefit, at least in part, from the cost savings that accrue under TEAM. For example, a beneficiary receiving a procedure under TEAM may benefit from a hospital's care coordination efforts regarding care during the inpatient hospital stay. The same beneficiary may be attributed to a primary care physician affiliated with an ACO who is actively engaged in coordinating care for all the beneficiary's clinical conditions throughout the entire performance year, beyond the 30-day post-discharge period of the episode.

We propose that a beneficiary could be in an episode in TEAM, as described in section X.A.3.b. of the preamble of this proposed rule, by undergoing a procedure at a TEAM participant, and be attributed to a provider participating in a total cost of care or shared savings model or program. For example, a beneficiary may be attributed to a provider participating in the Shared Savings Program for an entire performance year, as well as have initiated an episode in TEAM during the ACO's performance year. Each model or program incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. We propose to allow any savings generated on an episode in TEAM and any contribution to savings in the total cost of care model be retained by each respective participant. This would mean the episode spending in TEAM would be accounted for the in the total cost of care model's total expenditures, but TEAM's reconciliation payment amount or repayment amount would not be included in the total cost of care model's total expenditures. Likewise, the total cost of care model's savings payments or losses would not be included in the episode spending in TEAM.

By allowing a beneficiary aligned to a total cost of care model participant to also be attributed to an episode in TEAM, we would be eliminating complexities experienced in prior models where it was difficult for participants to know when a beneficiary would trigger an episode and when the episode would be excluded. In prior models such as BPCI, we implemented a recoupment process after reconciliation to account for any duplicative savings generated on overlapping beneficiaries. This process involved disbursing reconciliation payments to BPCI participants and then submitting a recoupment demand for any savings generated on overlap. Overwhelming feedback from participants indicated that this recoupment process was perceived negatively and postured participants in BPCI and the total cost of care model into an adversarial relationship. Allowing overlap between beneficiaries aligned to a total cost of care model who also initiate an episode in TEAM and by allowing both participants to retain savings will have a positive impact on beneficiaries by fostering a cooperative relationship between accountable care and TEAM participants where all parties have interest in providing coordinated, longitudinal care.

Allowing overlap does mean that episode expenditures will be included in ACO expenditures and thus, have a potential impact on ACO performance. Whether or not this benefits an ACO's shared savings involves a variety of contributing factors that span beyond merely the results of episodes in TEAM. For example, an ACO's size and volume of aligned beneficiaries or the dynamics of certain markets in which an ACO operates could impact an ACO's expenditure calculations and shared savings. CMS cannot isolate each variable that could influence an ACO's expenditures and shared savings, nor can CMS propose a singular policy that will ensure all ACOs benefit from interaction, or lack thereof, with TEAM.

[644] The Medicare Shared Savings Program benchmark updates include retrospective county-level trends that implicitly reflect BPCI Advanced and CJR spending changes; such methodology helps mitigate potential overlap of federal outlays.

[645] The CJR model only allows overlap with the BASIC track of the Medicare Shared Savings Program.

[646] Navathe, A.S., Liao, J.M., Wang, E., Isidro, U., Zhu, J., Cousins, D., & Werner, R.M. (2021). Association of patient outcomes with bundled payments among hospitalized patients attributed to accountable care organizations. JAMA Health Forum, 2(8), e212131. *https://doi.org/10.1001/jamahealthforum.2021.2131.*

But because TEAM will be mandatory in specific markets, the model will be generally expected to similarly impact a Shared Savings Program ACO's episode spending and corresponding regional episode spending that contributes most of its retrospective benchmark update. This interaction is anticipated to largely mitigate potential overlapping incentive payments for the largest ACO program in traditional Medicare. CMS believes that allowing overlap and the retention of savings by ACOs and TEAM participants will encourage providers to collaboratively deliver coordinated care and yield improved outcomes to beneficiaries. This aligns with broader agency goals to foster increased beneficiary alignment to value-based care and allows us to learn from experience and avoid creating challenges managing shared beneficiaries between ACOs and episodes of care participants. In addition, there are other potential benefits to allowing overlap between a beneficiary aligned to a total cost of care model and initiate an episode in TEAM, such as strengthening the volume of episodes a TEAM participant is responsible for. We know from prior experience that low episode volume creates challenges for participants to generate meaningful savings and manage outlier cases with unusually high episode expenditures.

We also acknowledge that certain ACOs may prefer for their aligned beneficiary population to not be included in TEAM. Since ACOs are accountable for total cost of care, they may prefer to manage their beneficiaries and have full control over all expenditures and beneficiary care instead of sharing that responsibility with a TEAM participant. Alternatively, we seek comment on prohibiting aligned beneficiaries from full-risk population-based care relationships (for example, Shared Savings Program Enhanced Track) from being in an episode in TEAM. We seek comment specifically on non-condition specific care relationships (that is, this would exclude condition-specific models such as the Enhancing Oncology Model (EOM)).

Additionally, we seek comment on the use of supplemental data (for example, shadow bundles[647] data) as providing a total cost of care or shared savings model participant with the ability to utilize episodes to improve care coordination and reduce cost.

(a) Considerations for Notification Process for Shared Savings or Total Cost of Care Model

Prior model experience has shown that it can be challenging for model participants to understand in real time whether a beneficiary's episode will be excluded, and we know that prior recoupment policies created friction between episode model participants and total cost of care model participants. We recognize the importance of coordination between a TEAM participant and total cost of care participant to ensure the beneficiary has continuous care moving beyond the structure of an episode. In order to accommodate a smooth transition for the aligned beneficiary, we considered, but are not proposing there be a notification process required of the TEAM participant to ensure they are alerting the total cost of care participant of their aligned beneficiary's episode during the anchor hospitalization or anchor procedure. This notification process would allow the total cost of care participant the time to deploy their resources (for example, care coordination staff) and be prepared as the patient discharges from their anchor hospitalization or anchor procedure. However, we recognize that identifying beneficiaries aligned to a total cost of care participant may be challenging because it would require timely access to beneficiary alignment list for total cost of care participants and would increase burden to implement a notification process. We seek comment on ways to implement a notification process for shared savings or total cost of care participants that would be used to alert a shared savings or total cost of care participant that one of their aligned beneficiaries has initiated an episode in TEAM.

Many total cost of care models (that is, ACOs) use their market's Health Information Exchange (HIE) to provide admission, discharge, and transfer (ADT) alerts. Others use less automated processes including fax or telephone to provide the alert. We recognize there is variation in the capabilities and sophistication of HIEs nationally and we recognize there is an increased administrative burden on participants when providing a telephonic or fax alert. Additionally, we recognize that there is a variation in the timeframe in which these alerts can be issued based on the mechanism in which they are provided. We seek comment on what timeframe should be required to issue the notification and what process(es) should be used to provide the notification without causing undue burden on the TEAM participant, including both the processes cited previously or other processes not mentioned. We also seek comment on how broader use of ADT data exchange between TEAM participants and ACOs could improve care coordination, including any perceived barriers to better ADT exchange, and opportunities to improve ADT exchange, and how CMS could address these barriers and opportunities.

(b) Accounting for Beneficiary Overlap With New CMS Models and Programs

We acknowledge there may be new models or programs that could have overlap with TEAM. This could occur because a beneficiary may trigger an episode in TEAM while being aligned to a new CMS model or program or because a TEAM participant also participates in another CMS model or program. We would plan to assess each new model to determine if the structure of payment and savings calculation are subject to the current proposed overlap policy or if there would be a need to bring forward any additional overlap requirements to account for the new model.

f. Health Equity

(1) Background

Consistent with President Biden's Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' and Executive Order 14091 on ''Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' CMS has made advancing health equity the first pillar in its Strategic Plan.[648] [649] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes. We are working to advance health equity by designing,

[647] Shadow bundles are claims data for services, supplies, and their associated payments grouped into discrete procedural- and/or condition-specific episodes of care. Episodes are constructed based on a consistent set of rules for ACO-attributed beneficiaries who meet the criteria to trigger an episode. Target prices are incorporated to measure performance and provide opportunity for sharing savings with providers.

[648] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[649] 88 FR 10825 (February 22, 2023) (*https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal*).

implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[650]

Disparities in access to surgical care by race/ethnicity, insurance status, income, and geography are well-documented, including disparities in the progression to surgery once surgical indication is determined and disparities in receipt of optimal surgical care.[651] Research has also highlighted disparities in readmissions rates following surgical intervention, indicating opportunities to tailor readmission-focused interventions to specific sites of care, such as safety net hospitals, to improve surgical outcomes.[652] [653] For Medicare beneficiaries, higher health-related social need is also associated with a higher risk of complications, length of stay, and 30-day readmission, and mortality following surgery.[654] Accordingly, there are opportunities to improve disparities in surgical outcomes by transforming infrastructure and care delivery processes, particularly for hospitals that serve higher proportions of historically underserved populations.

In this section, we discuss proposals for identifying safety net hospitals and rural hospitals within TEAM, and the associated flexibilities for TEAM participants meeting these definitions. We are seeking comment on the proposed safety net hospital and rural hospital definitions for TEAM, proposed model flexibilities for participants meeting each of these definitions, and the alternatives discussed.

(2) Identification of Safety Net Hospitals

(a) Background

Among the goals of CMS's health equity pillar is to evaluate policies to determine how we can support safety net providers, partner with providers in underserved communities, and ensure care is accessible to those who need it.[655] There are also opportunities to engage more safety net providers in CMS Innovation Center models to increase the diversity of Medicare beneficiaries reached by models.[656] Although various approaches exist to identify ''safety net providers,'' this term is commonly used to refer to health care providers that furnish a substantial share of services to uninsured and low-income patients.[657] As such, safety net providers, including acute care hospitals, play a crucial role in the advancement of health equity by making essential services available to the uninsured, underinsured, and other populations that face barriers to accessing healthcare, including people from racial and ethnic minority groups, the LGBTQ+ community, rural communities, and members of other historically disadvantaged groups. Whether located in urban centers or geographically isolated rural areas, safety net hospitals are often the sole providers in their communities of specialized services such as burn and trauma units, neonatal care and inpatient psychiatric facilities.[658] They also frequently partner with local health departments and other institutions to sponsor programs that address homelessness, food insecurity and other social determinants of health, and offer culturally and linguistically appropriate care to their patients.

Because they serve many low-income and uninsured patients, safety net hospitals may experience greater financial challenges compared to other hospitals. Among the factors that negatively impact safety net hospital finances, MedPAC has pointed specifically to the greater share of patients insured by public programs, which it stated typically pay lower rates for the same services than commercial payers; the increased costs associated with treating low-income patients, whose conditions may be complicated by social determinants of health, such as homelessness and food insecurity; and the provision of higher levels of uncompensated care.[659]

In its June 2022 Report to Congress, MedPAC expressed concern over the financial position of safety net hospitals.[660] The Commission noted that the limited resources of many safety net hospitals may make it difficult for them to compete with other hospitals for labor and technology, and observed that ''[t]his disadvantage, in turn, could lead to difficulty maintaining quality of care and even to hospital closure.'' [661] Other research shows that the closure of a safety net hospital can have ripple effects within the community, making it more difficult for disadvantaged patients to access care and shifting uncompensated care costs onto neighboring facilities.[662] [663]

Given the critical importance of safety net hospitals to the communities they serve, we have considered different safety net hospital definitions to identify the best way to represent providers serving historically underserved populations in TEAM and/or provide flexibilities to those deemed as safety net providers. In the following section, we discuss multiple methodological options for identifying safety net providers in TEAM.

(b) Methodological Considerations

(i) CMS Innovation Center Strategy Refresh Safety Net Definition

The CMS Innovation Center's Strategy Refresh developed a definition of safety net providers to monitor the percent of safety net facilities participating in CMS Innovation Center models. The CMS Innovation Center's Strategy Refresh defined safety net hospitals as short-term hospitals and critical access hospitals (CAHs) that serve above a

[650] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[651] de Jager E, Levine AA, Udyavar NR, et al. Disparities in Surgical Access: A Systematic Literature Review, Conceptual Model, and Evidence Map. J Am Coll Surg. 2019;228(3):276–298. doi:10.1016/j.jamcollsurg.2018.12.028 *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6391739/.*

[652] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. *Ann Surg.* 2014;259(6):1086–1090. doi:10.1097/SLA.0000000000000326. *https://pubmed.ncbi.nlm.nih.gov/24441810/.*

[653] Paredes AZ, Hyer JM, Diaz A, Tsilimigras DI, Pawlik TM. Examining healthcare inequities relative to United States safety net hospitals. *Am J Surg.* 2020;220(3):525–531. doi:10.1016/j.amjsurg.2020.01.044 *https://pubmed.ncbi.nlm.nih.gov/32014296/.*

[654] Paro A, Hyer JM, Diaz A, Tsilimigras DI, Pawlik TM. Profiles in social vulnerability: The association of social determinants of health with postoperative surgical outcomes. *Surgery.* 2021;170(6):1777–1784. doi:10.1016/j.surg.2021.06.001 *https://pubmed.ncbi.nlm.nih.gov/34183179/.*

[655] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[656] *https://www.healthaffairs.org/content/forefront/advancing-health-equity-through-cms-innovation-center-first-year-progress-and-s-come.*

[657] *https://www.ncbi.nlm.nih.gov/books/NBK224519/.*

[658] *https://www.ncbi.nlm.nih.gov/books/NBK224521/.*

[659] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[660] The June 2022 Report sets forth a conceptual framework for identifying safety-net hospitals and a rationale for better-targeted Medicare funding for such hospitals through a new Medicare Safety-Net Index (MSNI), as discussed in more detail later in this request for information. In its March 2023 Report to Congress, MedPAC discusses its recommendation to Congress to redistribute disproportionate share hospital and uncompensated care payments through the MSNI: *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

[661] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[662] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3272769/.*

[663] *https://www.healthaffairs.org/do/10.1377/forefront.20180503.138516/full/.*

baseline threshold of beneficiaries with dual eligibility or Part D Low-Income Subsidy (LIS), as a proxy for low-income status.[664] Under the CMS Innovation Center's Strategy Refresh definition, hospitals are identified as safety net when their patient mix of beneficiaries with dual eligibility or Part D LIS exceeds the 75th percentile threshold for all congruent facilities who bill Medicare.

To calculate the hospital-level proportions of beneficiaries with dual eligibility and Part D LIS, a one-year or multiple-year retrospective baseline (for example, weighted three-year average) for each measure could be calculated for each TEAM participant. We would then determine the 75th percentile threshold for each measure separately based on the distribution of the two proportions (beneficiaries with dual eligibility or Part D LIS) for all PPS hospitals who bill Medicare. TEAM participants with proportions that meet or exceed the determined threshold for either dual eligibility or Part D LIS will be considered as a safety net hospital for the purposes of TEAM.

We could make safety net determinations based on the CMS Innovation Center's Strategy Refresh's definition using the described approach as of the model start date and hold the determinations constant for TEAM's duration. Alternatively, we could calculate the hospital-level proportions of beneficiaries with dual eligibility and Part D LIS and the corresponding 75th percentile threshold for each measure annually, using a single year or rolling multiple-year weighted average of data from all PPS hospitals who bill Medicare. We could then make redeterminations of safety net qualification under TEAM annually. This annual approach could mean that TEAM participants' safety net hospital qualifications could vary over the model's duration.

(ii) Medicare Safety Net Index (MSNI)

Another approach to identify safety net hospitals would be to use MedPAC's Safety Net Index (SNI), which is calculated as the sum of—(1) the share of the hospital's Medicare volume associated with low-income beneficiaries; (2) the share of its revenue spent on uncompensated care; and (3) an indicator of how dependent the hospital is on Medicare. MSNI is calculated at the hospital level using data from CMS cost reports for each hospital.[665]

For the share of the hospital's Medicare volume associated with low-income beneficiaries, MedPAC's definition of low-income beneficiaries includes all those who are dually eligible for full or partial Medicaid benefits, and those who do not qualify for Medicaid benefits in their states but who receive the Part D LIS because they have limited assets and an income below 150 percent of the Federal poverty level. Collectively, MedPAC refers to this population as ''LIS beneficiaries'' because those who receive full or partial Medicaid benefits are automatically eligible to receive the LIS. MedPAC states that its intent in defining low-income beneficiaries in this manner is to reduce the effect of variation in states' Medicaid policies on the share of beneficiaries whom MedPAC considers low-income, but to allow for appropriate variation across states based on the share of beneficiaries who are at or near the Federal poverty level. To calculate the LIS ratio for a hospital for a given fiscal year, we could use the number of inpatient discharges of Medicare beneficiaries who are also LIS beneficiaries, using the most recent MedPAR claims for the discharge information, divided by the total number of inpatient discharges of Medicare beneficiaries.

For the share of a hospital's revenue spent on uncompensated care, we could use the ratio of uncompensated care costs to total operating hospital revenue from the most recent available audited cost report data.[666] For further discussion on how this ratio could be calculated using audited cost report, please refer to 88 FR 26658.

For the indicator of how dependent a hospital is on Medicare, MedPAC's recommendation is to use one-half of the Medicare share of total inpatient days. In calculating the Medicare share of total inpatient days for a hospital, we could use the most recent available audited cost report data. For further information on how the numerator and denominator could be determined to calculate the indicator of how dependent a hospital is on Medicare from audited cost report data, please refer to 88 FR 26658.

Using the sum of the three indicators as described, each TEAM participant could be assigned an SNI score, where a higher value means that a participant has either a high Medicare share of services, low incomes among a high share of its Medicare patients, and/or a high share of its revenue spent on uncompensated care.

To apply the Medicare Safety Net Index (MSNI) to identify safety net hospital participants in TEAM, we could calculate the SNI for TEAM *participants* using a one-year or multiple-year baseline period (for example, a three-year average). We could then set a threshold to identify safety net providers with TEAM based on the distribution of scores for all PPS hospitals that bill Medicare (for example, providers with scores in the 75th percentile of SNI scores could be considered safety net providers). We could make safety net determinations based on the described approach as of the model start date and hold the determinations constant for TEAM's duration. Alternatively, we could calculate the SNI and corresponding threshold annually using a one-year or multiple-year moving average and make redeterminations of safety net designations annually. This annual approach could mean that TEAM participant safety net qualifications for TEAM could vary over the model's duration.

(iii) Area Deprivation Index

Another approach to identifying safety net hospitals could be to use area-level indices. This approach could potentially better target policies to address the social determinants of health as well as address the lack of community resources that may increase risk of poor health outcomes and risk of disease in the population. In a recent environmental scan, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) suggested that an area-level index could be used to prioritize communities for funding and other assistance to improve social determinants of health (SDOH)—such as affordable housing, availability of food stores, and transportation infrastructure. Although ASPE concluded that none of the existing area-level indices identified in the environmental scan were ideal, they concluded that the area deprivation index (ADI) was one of the best available choices when selecting an index for addressing health related

[664] *https://www.cms.gov/priorities/innovation/data-and-reports/2022/cmmi-strategy-refresh-imp-tech-report.*

[665] MedPAC. ''March 2023 Report to Congress: Medicare Payment Policy, Chapter 3''. *https://www.medpac.gov/document/chapter-3-hospital-inpatient-and-outpatient-services-march-2023-report/.*

[666] The most recent available cost report data for this purpose generally lags 4 years behind the rulemaking year (for example, FY 2020 cost report data are available for this FY 2024 proposed rule).

social needs or social determinants of health.[667]

The ADI was developed through research supported by the National Institutes of Health'' (NIH) with the goal of quantifying and comparing social disadvantage across geographic neighborhoods. It is a composite measure derived through a combination of 17 input variables—including measures of income, education, employment, and housing quality—from the American Community Survey (ACS) 5-year estimate datasets.[668] Each neighborhood is assigned an ADI value from 1 to 100 (corresponding to percentile), where a higher value means that a neighborhood is more deprived. The ADI measure is intended to capture local socioeconomic factors correlated with medical disparities and underservice. Several peer reviewed research studies demonstrate that neighborhood-level factors for those residing in disadvantaged neighborhoods also have a relationship to worse health outcomes for these residents.[669] [670] [671]

Medicare already uses ADI to assess underserved beneficiary populations in the Shared Savings Program, and ADI is also used in CMS Innovation Center models. In the CY 2023 PFS final rule, CMS adopted a policy to provide eligible Accountable Care Organizations (ACOs) with an option to receive advanced investment payments (87 FR 69778). Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs in order to support care improvement for underserved beneficiaries (87 FR 69845 through 69849). The risk-factors based (using ADI) scores assigned to the beneficiaries assigned to the ACO form the basis for determining the quarterly advanced investment payment to the ACO. For additional detail, please see the quarterly payment amount calculation methodology at 42 CFR 425.630(f)(2).

To use ADI to identify safety net hospitals for TEAM, episodes could be assigned an ADI value based on the beneficiary's address found in the Common Medicare Environment (CME) file. Episodes meeting an established national ADI percentile threshold (for example, ADI >80) could be classified as high-ADI episodes, and a distribution of the proportion of high-ADI episodes could be constructed. Those TEAM participants that fell above an established threshold of high-ADI episodes (for example, 75th percentile) could be classified as safety net hospitals. For PY1, the proportion of high-ADI episodes and its corresponding distribution could be determined based on a single-year or multiple-year retrospective baseline (for example, three-year average). Those TEAM participants that met or exceeded the determined threshold would be designated as safety net. We could hold these designations constant for TEAM's duration or recalculate the proportion of high-ADI episodes annually (using a one-year or multiple-year moving average) and make safety net redeterminations based on an updated threshold on an annual basis. This annual approach could mean that TEAM participants' safety net qualifications for TEAM could vary over the model's duration.

(c) Proposed Methodology for Identifying Safety Net Hospitals

We considered the previously mentioned methods for identifying safety net hospitals and we propose to use the CMS Innovation Center's Strategy Refresh definition for identifying safety net hospitals within TEAM. Use of the CMS Innovation Center's Strategy Refresh's safety net definition allows for a consistent and streamlined approach to how the CMS Innovation Center plans to monitor safety net participation with CMS Innovation Center models. Further, the definition uses two recognized measures of social risk to identify hospitals serving a higher proportion of beneficiaries that may face barriers to receiving or accessing care.

Beneficiaries with dual eligibility are considered a vulnerable group for several reasons including the nature of dual eligibility requirements, a higher proclivity for experiencing chronic conditions, and an increased likelihood of mental health diagnosis.[672] [673] In its 2016 ''Report to Congress Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs,'' the Office of the Assistant Secretary for Planning and Evaluation (ASPE) found that dual eligibility status was the strongest predictor of poor outcomes of quality measures among multiple social risk factors examined.[674] TEAM's proposed approach to identify safety net hospitals is also similar to other approaches used in CMS Innovation Center models. For example, BPCI Advanced identifies safety net hospitals by tabulating the proportion of episodes with fully or partially dual eligible beneficiaries; if a hospital exceeded a 60% threshold of episodes based on the previous model year, then they would be considered a safety net hospital.[675]

While dual eligibility status does not fully capture all aspects of social risk, the incorporation of the proportion of patients with Part D LIS as a proxy for income into TEAM's proposed safety net definition broadens the range of possible beneficiary social risk factors used to make safety net hospital designations under the model. In its 2017 report on ''Accounting for Social Risk Factors in Medicare Payment,'' the National Academies found that accounting for dual eligibility alone may not be sufficient to capture all social risk factors, and the incorporation of multiple measures may help to better characterize overall social risk.[676]

We seek comment on our proposal to identify safety net hospitals using the CMS Innovation Center's Strategy Refresh's definition in TEAM at § 512.505.

(3) Identification of Rural Hospitals

(a) Background

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and

[667] Report: ''Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments.'' Accessed at *https://aspe.hhs.gov/reports/area-level-measures-account-sdoh* on September 27, 2022.

[668] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[669] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[670] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[671] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

[672] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_Factsheet.pdf.*

[673] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/NationalProfile_2012.pdf.*

[674] *https://aspe.hhs.gov/reports/report-congress-social-risk-factors-performance-under-medicares-value-based-purchasing-programs.*

[675] *https://www.cms.gov/files/document/bpcia-model-trg-price-specs-my7.pdf.*

[676] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press. doi: 10.17226/23635.

they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.[677] The health care inequities that many rural Americans face raise serious concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed. Barriers such as workforce shortages can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.[678]

Hospitals in rural areas often face other unique challenges. Rural hospitals may be the only source of healthcare services for beneficiaries living in rural areas, and beneficiaries have limited alternatives. Rural hospitals may also be in areas with fewer providers including fewer physicians and PAC facilities, rural hospitals may have more limited options in coordinating care and reducing spending while maintain quality of care under a value-based care arrangement. We believe that urban hospitals may not have similar concerns as they are often in areas with many other providers and have greater opportunity to develop efficiencies.

(b) Definition of Rural Hospital

We do not propose to include any geographically rural areas for TEAM based on the proposed CBSAs as defined in section X.A.3.a.(4) of the preamble of this proposed rule. However, some hospitals in the proposed CBSAs for TEAM may be considered rural for other reasons, such as being reclassified as rural under the Medicare wage index regulations or being designated a rural referral center (RRC).

For the purposes of TEAM, we propose a rural hospital to mean an IPPS hospital that is located in a rural area as defined under § 412.64 of this chapter; is located in a rural census tract defined under § 412.103(a)(1) of this chapter; has reclassified as a rural hospital under § 412.103 of this chapter, or is designated a rural referral center (RRC) under § 412.96 of this chapter. This definition would be an expanded version of the rural hospital definition used by the CJR model as defined in 42 CFR 510.

For PY1, rural designations under TEAM would be based on the TEAM participant's rural classification as of the model start date. We recognize that rural designations and rural reclassification requests in accordance with § 412.103 may occur over on a rolling basis over the course of the model and can take several months to be reviewed and approved by CMS. TEAM participants that receive an approved rural designation under the criteria defined in the preceding paragraph or an approved rural reclassification in accordance with § 412.103 must notify CMS at least 60 calendar days prior to the start of a model's performance year for CMS to consider classifying the TEAM participant as rural under the model for the following performance year. We propose that model rural designations will occur only once at the beginning of each model performance year regardless of when a TEAM participant's rural classification may change within a given performance year.

We propose that if a TEAM participant's classification is no longer rural pursuant to § 412.103 or any other criteria previously qualifying them as rural as defined earlier in this section, the TEAM participant must notify CMS in a manner chosen by CMS within 60 calendar days of receipt of this designation change. We propose that TEAM participants would continue to receive the flexibilities for rural hospitals as described in section X.A.3.a.(3) of the preamble of this proposed rule through the remainder of the performance year in which the redesignation occurs, but the TEAM participant would no longer qualify for rural hospital flexibilities at the start of the next performance year.

We seek comment on our proposal to identify rural hospitals in this section. We are not proposing to include a measure of hospital rurality within our risk adjustment model as described in sectionX.A.3.d.(4) of the preamble of this proposed rule but seek comments on whether inclusion of this risk adjustor would be warranted.

(4) Beneficiary Social Risk Adjustment

In recent years there has been a push for Medicare and other payers to include beneficiary social risk adjustment into financial methodologies that determine health care payments.[679] It is believed that the inclusion of beneficiary social risk adjustment may provide more resources to providers who care for underserved beneficiaries to offset the additional costs often attributed to SDOH. In other words, patients with limited resources or access to care may require more spending from providers to achieve equitable outcomes. Beneficiary social risk adjustment has been limited in previous episode-based payment models. The BPCI Advanced and CJR models included beneficiary social risk adjustment for beneficiary dual eligibility status, yet that single adjuster alone may not be sufficient in capturing spending differences for beneficiary social risk. Findings from the CJR model's 5th Annual Report found that, during the baseline period, historically underserved populations generally had higher episode payments, used more institutional post-acute care, had higher rates of emergency department use and readmissions, and received elective LEJRs at a lower rate than their reference populations.[680]

There is significant literature and research surrounding the inclusion of social risk adjustment in health care payments, especially given the varying social risk adjustment indicators available.[681] [682] [683] In a recent environmental scan, ASPE indicated that area-level deprivation indices tend to have the broadest coverage across the entire range of social risk factors. According to ASPE's report, area-level deprivation indices are, by definition, measured for geographic areas, which presents challenges in including them in payment models because a provider's patients are unlikely to be representative of the population of the

[677] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[678] Healthy People 2020 (n.d.) Access to Health Services. *https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services.*

[679] Adjusting Medicare payments for social risk to better support social needs. (2021). [Dataset]. In Forefront Group. *https://doi.org/10.1377/forefront.20210526.933567.*

[680] CMS Comprehensive Care for Joint Replacement Model: Performance Year 5 Evaluation Report. (2023). Centers for Medicare & Medicaid Services. Retrieved December 1, 2023, from *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report.*

[681] Powers, B., Figueroa, J.F., Canterberry, M., Gondi, S., Franklin, S.M., Shrank, W.H., & Maddox, K.E.J. (2023). Association between Community-Level Social Risk and spending among Medicare beneficiaries. JAMA Health Forum, 4(3), e230266. *https://doi.org/10.1001/jamahealthforum.2023.0266.*

[682] Irvin, J., Kondrich, A., Ko, M., Rajpurkar, P., Haghgoo, B., Landon, B.E., Phillips, R.L., Petterson, S., Ng, A.Y., & Basu, S. (2020). Incorporating machine learning and social determinants of health indicators into prospective risk adjustment for health plan payments. BMC Public Health, 20(1). *https://doi.org/10.1186/s12889-020-08735-0.*

[683] Addressing social risk factors in Value-Based Payment: Adjusting payment not performance to optimize outcomes and fairness. (2021). [Dataset]. In Forefront Group. *https://doi.org/10.1377/forefront.20210414.379479.*

geographic area in which the provider is located.[684]

Several CMS Innovation Center initiatives incorporate (or may incorporate) beneficiary social risk adjustment into their financial calculations or determining payment amounts, including the ACO REACH model, the Enhancing Oncology Model (EOM), the Making Care Primary (MCP) model, and the Guiding an Improved Dementia Experience (GUIDE) model. To avoid relying on a single indicator that may not be representative of the beneficiaries a provider cares for, these models incorporate multiple social risk indicators. Specifically, these models take into account one or more of the following indicators in their risk adjustment models: state and national ADI, Medicare Part D Low-Income Subsidy (LIS), and dually eligible beneficiaries enrolled in both Medicare and Medicaid. Factoring in multiple indices may avoid challenges when an underserved beneficiary lives in higher cost-of-care area or beneficiaries that have difficulty accessing care. For example, incorporating both state and national ADI allows the for the risk adjustment model to capture national and local socioeconomic factors correlated with medical disparities and underservice, while including the LIS measure will capture socioeconomic challenges that could affect a beneficiary's ability to access care. For these reasons, and to align with other CMS Innovation Center models, we propose to incorporate and equally weight three social risk indicators in TEAM's target price methodology, see section X.A.3.d.(4) of the preamble of this proposed rule, specifically state and national ADI indicators, the Medicare Part D LIS indicator, and Dual-eligibility status for Medicare and Medicaid. We believe that including these social risk indicators would ensure TEAM participants that serve disproportionately high numbers of underserved beneficiaries are not inadvertently penalized when setting TEAM target prices.

We seek comment on the proposed beneficiary social risk adjusters for TEAM and whether there are potential beneficiary social risk indicators we should consider in TEAM's target price methodology.

(5) Health Equity Plans and Reporting

(a) Health Equity Plans

We believe it is important for TEAM participants to identify and monitor where disparities exist in their TEAM beneficiary population, and to use the data that they collect to implement evidence-based strategies aimed at addressing the identified health disparities and advancing health equity. To further align with other CMS Innovation Center models and promote health equity, we are proposing that TEAM participants can voluntarily submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan for the first performance year. This proposal to make submission of a health equity plan voluntary in PY1 recognizes that constructing a health equity plan may require significant time and effort by the TEAM participant. Beginning in PY2, we propose that TEAM participants would be required to submit a health equity plan in a form and manner and by the date(s) specified by CMS. Beginning in PY2 for those TEAM participants that voluntarily submitted a health equity plan in PY1 and beginning in PY3 for those TEAM participants that first reported a health equity plan in PY2, we propose that the TEAM participant would submit updates to their previously submitted health equity plans in a form and manner and by date(s) specified by CMS. We propose that the health equity plans submitted in all performance years would include the following elements:

- Identifies health disparities. We propose to define ''health disparities'' as preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health, health quality, or health outcomes that are experienced by one or more ''underserved communities'' [685] within the TEAM participant's population of TEAM beneficiaries that the participant will aim to reduce. We propose to define ''underserved communities'' as populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.[686] We propose that the data sources used to inform the identification of health disparities should also be noted in the plan.
- Identifies health equity goals and describes how the TEAM participant will use the health equity goals to monitor and evaluate progress in reducing the identified health disparities. We propose to define ''health equity goals'' as targeted outcomes relative to the health equity plan performance measures for the first PYs and all subsequent PYs.
- Describes the health equity plan intervention strategy. We propose to define ''health equity plan intervention strategy'' as the initiative(s) the TEAM participant will create and implement to reduce the identified health disparities.
- Identifies health equity plan performance measure(s), the data sources used to construct the health equity plan performance measures, and an approach to monitor and evaluate the health equity plan performance measures. We propose to define ''health equity plan performance measure(s)'' as one or more quantitative metrics that the TEAM participant will use to measure changes in health disparities arising from the health equity plan interventions.

We solicit comment on the proposed voluntary health equity plan submission in PY1 and mandatory health equity plan submission in PY2 and all following performance years as proposed in § 512.563. We also solicit comment on whether TEAM participants should be required to submit a health equity plan in PY2 and for all subsequent performance years if a TEAM participant submits a health equity plan to CMS for another CMMI model in the same performance year, or if the TEAM participant should be required to submit a health equity plan that is specific to TEAM and the TEAM participant's population of TEAM beneficiaries. We also solicit comment on the proposed elements of the health equity plan.

(b) Demographic Data Reporting

We recognize disparities exist for beneficiaries in the health care system, including those receiving episodic care. Health care disparities highlight the importance of data collection and analysis that includes race, ethnicity, language, disability, sexual orientation, gender identity, and sex characteristics or other demographics by health care facilities. Such data are necessary for integration of health equity in quality programs, because the data permits stratification by patient

[684] Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments. (2022). Office of the Assistant Secretary for Planning and Evaluation. Retrieved December 1, 2023, from *https://aspe.hhs.gov/sites/default/files/documents/ce8cdc5da7d1b92314eab263a06efd03/Area-Level-SDOH-Indices-Report.pdf.*

[685] *https://www.cms.gov/priorities/innovation/key-concepts/health-equity#:~:text=(Source%3A%20CMS),underserved%20populations%20(Adapted%20from%20CDC).*

[686] *https://www.federalregister.gov/d/2021-01753/p-6.*

subpopulation.[687] [688] Stratified data can produce meaningful measures that can be used to expose health disparities, develop focused interventions to reduce them, and monitor performance to ensure interventions to improve care do not have unintended consequences for certain patients.[689] Furthermore, quality programs are carried out with well-known and widely used standardized procedures including but not limited to root cause analysis, plan-do-study-act (PDSA) cycles, health care failure mode effects analysis, and fish bone diagrams. These are common approaches in the health care industry to uncover the causes of problems, to show the potential causes of a specific event, test a change that is being implemented, prevent failure by correcting a process proactively, and identify possible causes of a problem and soft ideas into useful categories, respectively.[690] [691] [692] [693] Adding a health equity prompt to these standardized procedures integrates a health equity lens within the quality structure and cues considerations of the patient subpopulations who receive care and services from a hospital.[694]

To align with other CMS efforts, we are proposing that TEAM participants could voluntarily report to CMS demographic data of TEAM beneficiaries pursuant to 42 CFR 403.1110(b) in PY1. Beginning in PY2 and all subsequent performance years, we propose that TEAM participants would be required to report demographic data of TEAM beneficiaries to CMS in a form and manner and by a date specified by CMS. The demographic data would also be required to conform to USCDI version 2 data standards, at a minimum. Collection of this data could provide synergies with goals articulated in health equity plans of TEAM participants. Further, this expanded demographic data would allow CMS to gain more nuanced understanding of the expanded demographics of TEAM beneficiaries—including data on race, ethnicity, language, disability, sexual orientation, gender identity, sex characteristics, and other demographics—to monitor and evaluate the model.

We propose that in conducting the collection required beginning in PY2 under this section that the TEAM participant would make a reasonable effort to collect demographic data from all TEAM beneficiaries; however, we recognize this may require additional administrative effort to collect this data or identify TEAM beneficiaries that may elect to not provide this data. We recognize that CEHRT may help to reduce administrative burden once EHR platforms have been programmed to capture and exchange the types of demographic date elements of interest. We also recognize that this demographic data may already be reported to CMS for other CMS initiatives.

We seek comment on the proposed voluntary reporting of demographic data of TEAM beneficiaries in PY1 with mandatory reporting beginning in PY2 and all following performance years. As we wish to minimize reporting burden on TEAM participants to ensure sufficient time and effort is spent adjusting to the requirements of a mandatory model, we seek comments on how reporting of this demographic data could minimize burden and if it could be collected from existing data sources.

(c) Health Related Social Needs Data Reporting

The CMS Innovation Center is charged with testing innovations that improve quality and reduce the cost of health care. There is strong evidence that non-clinical drivers of health are the largest contributor to health outcomes and are associated with increased health care utilization and costs.[695] [696] These individual-level, adverse social conditions that negatively impact a person's health or healthcare are referred to as ''health-related social needs'' or HRSNs. CMS aims to expand the collection, reporting, and analysis of standardized HRSNs data in its efforts to drive quality improvement, reduce health disparities, and better understand and address the unmet social needs of patients. Standardizing HRSN screening and referral as a practice can inform larger, community-wide efforts to ensure the availability of and access to community services that are responsive to the needs of Medicare beneficiaries. While screening for HRSN is an important step to identify the unmet HRSNs of patients, it is also critical for providers to build referral relationships with community-based organizations and other social service organizations that can more directly support patients identified to have unmet HRSNs.

While more common nationally, HRSN screening is not uniform across geography or health care setting. A literature review of national surveys measuring prevalence of HRSN screening found that 56–77 percent of health care payers and/or delivery organizations screened for HRSN.[697] The review also found that almost half of state Medicaid agencies have established managed care contracting requirements for HRSN screening in Medicaid.[698] Despite screening proliferation and generally positive views toward screening among both patients and health care providers, implementation of screening and referral policies for beneficiaries of CMS programs with similar health—and even demographic—profiles may be inconsistent, potentially exacerbating disparities in the comprehensiveness and quality of care.

To help facilitate alignment of HRSN screening within inpatient settings, beginning in 2024, the Hospital Inpatient Quality Reporting Program began mandatory reporting of a Screening for Social Drivers of Health (SDOH–1) measure, the proportion of

[687] IOM (Institute of Medicine). 2009. *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (p.287). The National Academies Press *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[688] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[689] Weinick, R.M., & Hasnain-Wynia, R. (2011). Quality Improvement Efforts Under Health Reform: How To Ensure That They Help Reduce Disparities—Not Increase Them. *Health Affairs, 30*(10), 1837–1843. *https://doi.org/10.1377/hlthaff.2011.0617.*

[690] American Society for Quality. (2019). *What is root cause analysis (RCA)? Asq.org. https://asq.org/quality-resources/root-cause-analysis.*

[691] Agency for Healthcare Research and Quality. (2020). *Plan-Do-Study-Act (PDSA) directions and examples. Www.ahrq.gov. https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.html.*

[692] *Failure Modes and Effects Analysis (FMEA) Tool | IHI—Institute for Healthcare Improvement.* (2017). *Www.ihi.org. https://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx.*

[693] Kane, R. (2014). *How to Use the Fishbone Tool for Root Cause Analysis. https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fishbonerevised.pdf.*

[694] Sivashanker, K., & Gandhi, T.K. (2020). Advancing Safety and Equity Together. *New England Journal of Medicine, 382*(4), 301–303. *https://doi.org/10.1056/nejmp1911700.*

[695] Booske, B.C., Athens, J.K., Kindig, D.A., Park, H., & Remington, P.L. (2010). County Health Rankings (Working Paper). *https://www.countyhealthrankings.org/sites/default/files/differentPerspectivesForAssigningWeightsToDeterminantsOfHealth.pdf.*

[696] ROI Calculator for Partnerships to Address the Social Determinants of Health Review of Evidence for Health-Related Social Needs Interventions. (2019). *https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED-ROI-EVIDENCE-REVIEW-7-1-19.pdf.*

[697] De Marchis EH, Brown E, Aceves B, et al. State of the Science of Screening in Healthcare Settings. Social Interventions Research & Evaluation Network, 2022. *https://sirenetwork.ucsf.edu/tools-resources/resources/state-science-social-screening-healthcare-settings.*

[698] De Marchis EH, Brown E, Aceves B, et al. State of the Science of Screening in Healthcare Settings. Social Interventions Research & Evaluation Network, 2022. *https://sirenetwork.ucsf.edu/tools-resources/resources/state-science-social-screening-healthcare-settings.*

admitted adults screened for five HRSNs, and a Screen Positive Rate for Social Drivers of Health (SDOH–2) measure, the percentage of screened admitted adults that screened positive for one or more HRSN. The measures reflect screening for five HRSNs: housing instability, food insecurity, transportation needs, utility difficulties, and interpersonal safety. The CMS Innovation Center Strategy Refresh also established a goal to require all new models to collect and report demographic and social determinants of health (SDOH) data in support of broader system transformation that support goals of advancing health equity.

Beginning in PY1, we propose that TEAM participants would be required to screen attributed TEAM beneficiaries for at least four HRSN domains—such as but not limited to food insecurity, housing instability, transportation needs, and utilities difficulty—because we believe these areas are most pertinent for the TEAM beneficiary population. We also considered requiring TEAM participants to screen on a standardized set of HRSN domains.

We also propose that TEAM participants would need to report aggregated HRSN screening data and screened-positive data for each HRSN domain for TEAM beneficiaries that received screening to CMS in a form and manner and by date(s) specified by CMS beginning in PY1 and for all following performance years. As part of this reporting to CMS, we also propose that TEAM participants would report on policies and procedures for referring beneficiaries to community-based organizations, social service agencies, or similar organizations that may support patients in accessing services to address unmet social needs.

We recognize TEAM participants may already report some of this HRSN screening data through other CMS initiatives and requiring reporting of aggregated HRSN screening data in TEAM may be redundant. For example, the Hospital Inpatient Quality Reporting Program will begin mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination of two evidence-based measures related to HRSN screening: the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure (87 FR 49201 through 49220). We therefore seek comment on reporting processes that would streamline reporting of aggregated HRSN screening data for attributed TEAM beneficiaries, including potential use of the Hospital Inpatient Quality Report Program measures related to HRSN screening.

We also seek comment on how the reporting of aggregated HRSN screening data could incorporate data on referrals of beneficiaries screening positive for HRSNs to community-based organizations and other organizations helping to address beneficiaries' HRSNs.

(6) Other Considerations

In addition to the preceding health equity proposals, we seek comment on possibly providing upfront infrastructure payments to qualified safety net hospital participants to further support safety net hospitals in the transformation of care delivery. Subject to certain limitations, these funds could be available to cover approved expenses aimed at supporting beneficiaries with unmet health and social needs. Payment could support Health Information Technology (health IT)/Electronic Health Records (EHR) enhancements, to the extent they involve population health analytics, support care coordination with other providers within and across care settings, and support referrals to address HRSNs (such as closed loop community-based organization referrals). Participants might also use the infrastructure payment to fund the upfront expenses involved in recruiting dedicated staff (for example, care managers). Participants could distribute or use infrastructure payments received under this model in accordance with existing law or the terms of applicable waivers. Such funds would ensure the infrastructure of safety net hospitals could support the transformational goals of the model, and would not come out of the Medicare Parts A and B Trust Funds.

We believe that transformation of acute care delivery in underserved areas is fundamental to addressing persistent disparities and engaging safety net hospitals may broaden the landscape of clinicians focusing on value-based care. We would need to consider the amount of the infrastructure payment, which may include a standard fixed funding component and a variable component that depends on the size of the population served by the safety net hospital participant. We would also need to define a specific set of parameters and formula to calculate the infrastructure payment for each qualifying TEAM participant and seek feedback on the set of parameters we could consider using.

We seek feedback from hospitals and health IT vendors for estimates on the potential upfront start-up costs of health IT investments for safety net hospitals, such as new health information exchange capabilities, solutions to provide patients with access to their health data (for instance, patient portals), capabilities to capture patient-reported outcomes, event notification systems, and community referral capacity. Should we decide to provide such payments, we also expect the infrastructure improvement would require financial investment on the part of the participant, clinicians, and other payer partners, including those on the commercial side.

The goal of the infrastructure payment would be to assist safety net hospital participants, many of whom have less access to capital, participate in and be successful in this model. CMS recognizes that start-up and ongoing annual operating costs could vary greatly between participants for various reasons, including those related to the experience, size, and funding available to the participant.

Past CMS Innovation Center models have proven the utility of infrastructure payments in certain circumstances, which may or may not apply to TEAM. These models include the ACO Investment Model (AIM), a CMS Innovation Center model that tested the effects of making advanced payments to certain ACOs participating in the Shared Savings Program to assist them in transforming care by funding infrastructure investments or staffing. AIM ACOs overwhelmingly used these funds to invest in health IT systems and care management staff and to cover administrative and program compliance costs. At the start of the model, many AIM ACOs lacked the capacity and knowledge to implement population health initiatives, to manage claims-based analytics, and to coordinate practice management. The demonstrated Medicare savings by AIM ACOs suggest that financial accountability with upfront investments can succeed in allowing under-resourced clinicians serving underserved areas to deliver care more efficiently and afford them more flexibility in how they meet beneficiaries' needs without increasing Medicare spending.

To receive an infrastructure payment, we could consider the following requirements and seek comment on any changes: (1) require TEAM participants to be a safety net hospital, as defined by section X.A.3.f.(2)(c) of the preamble of this proposed rule. The TEAM participant would also submit a detailed plan that describes their intended use of the funds and how those funds would support the goals of the model and improve the care of underserved beneficiaries.

With respect to use of funds for technology investments that involve implementing, acquiring, or upgrading health IT, the hospital would also be required to ensure such technology is certified under the ONC Health IT Certification Program or utilizes nationally recognized, consensus-based standards adopted under section 3004 of the PHSA,[699] where such criteria or standards are available for the health IT-related activity. Use of these standards and certification criteria ensure that technology investments would support interoperability across systems. Should we make an infrastructure payment to a safety net hospital, we would need to monitor the spending of infrastructure payments to prevent funds from being misdirected and ensure they are used for activities that constitute a permitted use of the funds (for example, health IT/EHR enhancements to the extent those involve population health analytics and support for referrals to address HRSNs, in addition to costs associated with recruiting and hiring dedicated staff). In addition to the initial plan of anticipated spending, should a safety net hospital participant receive upfront funds, they could also be required to submit annual reports (in a standardized format specified by CMS) that includes an itemization of how infrastructure payments were actually spent during the performance year, including expenditure categories, the dollar amounts spent on the various categories, any changes to the spend plan, and such other information as may be specified by CMS. This itemization could include expenditures not identified or anticipated in the submitted spend plan and any amounts remaining unspent. Any infrastructure payments that are spent for unauthorized purposes or are unspent at the end of a specified timeframe, that is, 3 years, must be repaid to CMS.

Should safety net hospital participants receive such payments, they would be required to retain adequate records to ensure that we have the information necessary to conduct appropriate monitoring and oversight of the use of infrastructure payments (for example, invoices, receipts, and other supporting documentation of disbursements). CMS would need to conduct audits on a percentage of funding recipients annually to monitor and assess a safety net hospital participant's use of infrastructure funds and participant compliance related to such payments. To encourage speedy resolution of noncompliance and provide an added safeguard against abuse, if CMS determines that a participant has spent infrastructure funds on an identified prohibited use, has unspent funds at the end of the designated eligible spending period, otherwise fails to comply with infrastructure requirements, and/or meets any of the grounds for termination, CMS may require repayment equal to the amount of any infrastructure funds spent on a prohibited use.

As mandatory model, one consideration in potentially implementing an infrastructure payment for qualifying safety net hospital TEAM participants is the long-term scalability of the model. With the goal of longer-term expansion of the TEAM model, inclusion of a one-time infrastructure payment for qualifying safety net hospitals as part of model design could present challenges to the financial sustainability of the model. Accordingly, the potential objectives and benefits of the infrastructure payment would need to be considered against the feasibility of implementing this model feature should the model be expanded.

We seek comment on the considerations surrounding provision of infrastructure payments and their utility in the acute care setting, including how to identify participants most likely to benefit. We also seek comment on how best to ensure the integrity of such payments in supporting the goal of addressing known health disparities among the episode categories we are proposing to test via TEAM. We also seek comment on the proposed methodology and/or parameters that could be used in a formula to determine the infrastructure payment amounts for qualifying TEAM participants.

g. Financial Arrangements

(1) Background

We believe it is necessary to provide TEAM participants with flexibilities that could support their performance in TEAM and allow for greater support for the needs of beneficiaries. These flexibilities are outlined in this section and include the ability to engage in financial arrangements to share a TEAM participant's reconciliation payment amounts and repayment amounts. Such flexibilities would allow TEAM participants to share all or some of the TEAM participant's reconciliation payment amount or repayment amount. Finally, we believe that TEAM participants caring for beneficiaries may want to offer beneficiary incentives to encourage adherence to recommended treatment and beneficiary engagement in recovery. These financial and beneficiary incentives may help a TEAM participant reach their quality and efficiency goals for the model. They may also provide a benefit to beneficiaries and benefit the Medicare Trust Fund if the TEAM participant improves the quality and efficiency of care that results in reductions in hospital readmissions, complications, days in acute care, and mortality, while recovery continues uninterrupted or accelerates.

(2) Overview of TEAM Financial Arrangements

We believe that TEAM participants may wish to enter into financial arrangements with certain providers and suppliers participating in TEAM activities to share their reconciliation payment amount or repayment amount resulting from participation in TEAM. Allowing these types of financial arrangements would allow the alignment of financial incentives of those providers and suppliers participating in TEAM activities to improve quality of care, drive equitable outcomes, and reduce Medicare spending through improved beneficiary care transitions and reduced fragmentation following select episodes of care. We expect that TEAM participants would identify key providers and suppliers caring for beneficiaries in the surrounding communities, and then could establish partnerships with these individuals and entities to promote accountability for the quality, cost, and overall care for beneficiaries, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigning care processes for high quality and efficient service delivery; and carrying out other obligations or duties under TEAM . These providers and suppliers may invest substantial time and other resources in these activities, yet they would not be the direct recipients of any reconciliation payment amounts or repayment amounts as they are not the risk bearing entity and do not directly participate in TEAM. Therefore, we believe it is possible that a TEAM participant that may receive a reconciliation payment amount or repayment amount may want to enter into financial arrangements with other providers or suppliers to share this reconciliation payment amount or repayment amount with the TEAM participant. We expect that all financial

[699] For more information ONC Health IT Certification Criteria, see *https://www.healthit.gov/topic/certification-ehrs/certification-criteria.* For standards and implementation specifications adopted under PHSA section 3004, see 45 CFR part 170, subpart B.

relationships established between TEAM participants and providers or suppliers for purposes of TEAM would be those permitted only under applicable law and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. As discussed in section X.A.3.g.(9) of the preamble of this proposed rule, CMS expects, if the proposed arrangements are finalized, to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)) is available to protect certain remuneration proposed in this section when arrangements with eligible providers and suppliers are in compliance with the requirements established in the final rule and the conditions of the safe harbor for CMS-sponsored model arrangements established at 42 CFR 1001.952(ii).

We recognize that there are numerous arrangements that TEAM participants may wish to enter other than the financial arrangements described in the proposed regulations for which safe harbor protection may be extended that could be beneficial to the TEAM participants. For example, TEAM participants may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; beneficiary care coordination and management; monitoring TEAM participants' compliance with the model's terms and conditions; or other model-related activities. Such organizations may play important roles in a TEAM participant's plans to implement the model based on the experience these organizations may bring, such as prior experience with episode-based payment models, care coordination expertise, familiarity with a particular local, or knowledge of bundled data. We expect that all relationships established between TEAM participants and these organizations for purposes of the model would be those permitted only under existing law and regulation, including any relationships that would include the TEAM participant's sharing of the reconciliation payment amount or repayment amount. We would expect these relationships to be solely based on the level of engagement of the organization's resources to directly support the TEAM participants' model implementation.

(3) TEAM Collaborators

As proposed, TEAM is a two-sided financial risk model and the TEAM participant would bear sole financial risk for any repayment amount to CMS in the absence of financial arrangements. However, given the incentive to reduce episode spending to earn a reconciliation payment amount, as described in section X.A.3.d.(5)(j) of the preamble of this proposed rule, a TEAM participant may want to engage in financial arrangements with providers and suppliers or participants in Medicare ACO initiatives who are making contributions to the TEAM participant's performance in the model. Such arrangements would allow the TEAM participant to share reconciliation payment amounts or repayment amounts with individuals and entities that have a role in the TEAM participant's performance in the model. We propose to use the term ''TEAM collaborator'' to refer to these individuals and entities.

Because TEAM participants would be accountable for spending and quality during the anchor hospitalization or anchor procedure and the 30-day post discharge period, as described in section X.A.3.b.(5) of the preamble of this proposed rule, providers and suppliers other than the TEAM participant may furnish services to the beneficiary during the model performance period. As such, for purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose at § 512.505 that the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare or entities that are participating in a Medicare ACO initiative may be TEAM collaborators:

- Skilled Nursing Facility (SNF).
- Home Health Agency (HHA).
- Long-Term Care Hospital (LTCH).
- Inpatient Rehabilitation Facility (IRF).
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.
- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy group practice (TGP).
- Medicare ACO.

We seek comment on the proposed definition of TEAM collaborators and any additional Medicare-enrolled providers or suppliers, such as Rural Emergency hospitals, Rural Health Clinics, and Federally Qualified Health Centers, that should be included in this definition.

(4) Sharing Arrangements

(a) General

Similar to the CJR Model (42 CFR 510.500), we propose that certain financial arrangements between a TEAM participant and a TEAM collaborator be termed ''sharing arrangements.'' For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose that a sharing arrangement would be to share reconciliation payment amounts or repayment amounts. Where a payment from a TEAM participant to a TEAM collaborator is made pursuant to a sharing arrangement, we propose to define that payment as a ''gainsharing payment,'' which is discussed in section X.A.3.g.(4)(c) of the preamble of this proposed rule. Where a payment from a TEAM collaborator to a TEAM participant is made pursuant to a sharing arrangement, we propose to define that payment as an ''alignment payment,'' which is discussed in section X.A.3.g.(4)(c) of the preamble of this proposed rule. A TEAM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. We propose that a sharing arrangement must comply with the provisions of section X.A.3.g.(b) of the preamble of this proposed rule. And all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. We propose that the TEAM participant and TEAM collaborator must document this agreement in writing and, per monitoring and compliance guidelines (§ 512.590), we propose that it must be made available to CMS upon request.

We propose that the TEAM participant must develop, maintain, and use a set of written policies for selecting individuals and entities to be TEAM collaborators. To safeguard against potentially fraudulent or abusive practices, we propose that the selection criteria determined by the TEAM participant must include the quality of care delivered by the potential TEAM collaborator. Moreover, the selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, or any individual or affiliated with a TEAM participant, TEAM collaborator, or collaboration agent. In addition to including quality of care in their selection criteria, TEAM participants must also consider selection of TEAM

collaborators based on criteria that include the anticipated contribution to the performance of the TEAM participant in the model by the potential TEAM collaborator to ensure that the selection of TEAM collaborators takes into consideration the likelihood of their future performance.

Finally, we propose that if a TEAM participant enters a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of the model. Requiring oversight of sharing arrangements to be included in the compliance program provides a program integrity safeguard.

We seek comment about all provisions described in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(b) Requirements

We propose several requirements for sharing arrangements to help ensure that their sole purpose is to create financial alignment between TEAM participants and TEAM collaborators toward the goals of the model while maintaining adequate program integrity safeguards. We propose that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to TEAM beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. It is important that providers and suppliers rendering items and services to beneficiaries during the model performance period have the freedom to provide medically necessary items and services to beneficiaries without any requirement that they participate in a sharing arrangement to safeguard beneficiary freedom of choice, access to care, and quality of care. The sharing arrangement must set out the mutually agreeable terms for the financial arrangement between the parties to guide and reward model care redesign for future performance toward model goals, rather than reflect the results of model performance years that have already occurred and where the financial outcome of the sharing arrangement terms would be known before signing.

We propose that the sharing arrangement must require the TEAM collaborator and its employees, contractors, and subcontractors to comply with certain requirements that are important for program integrity under the arrangement. We note that the terms contractors and subcontractors include collaboration agents as defined later in this section. The sharing arrangement must require all of the individuals and entities party to the arrangement to comply with the applicable provisions of this proposed rule, including proposed requirements regarding beneficiary notifications, at proposed § 512.582(b), access to records and record retention, at proposed § 512.586, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees, at proposed § 512.590 because these individuals and entities all would play a role in model care redesign and be part of financial arrangements under the model as proposed. The sharing arrangement must also require all individuals and entities party to the arrangement who are providers or suppliers to comply with the applicable Medicare provider enrollment requirement at § 424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement. This proposed requirement is to ensure that the individuals and entities have the required enrollment relationship with CMS under the Medicare program, although we note that they are not responsible for complying with requirements that do not apply to them. Finally, the sharing arrangement must require individuals and entities to comply with all other applicable laws and regulations.

We propose that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between TEAM participants and TEAM collaborators do not negatively impact beneficiary protections under the model. The sharing arrangement as proposed must require the TEAM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the model, just as we require TEAM participants to have a compliance program that covers oversight of the sharing arrangement for this purpose as a program integrity safeguard. We seek comment on the anticipated effect of the proposed compliance program requirement for TEAM collaborators, particularly with regard to individual physicians and nonphysician practitioners, small PGPs, NPPGPs, and TGPs and whether alternative compliance program requirements for all or a subset of TEAM collaborators should be adopted to mitigate any effect of the proposal that could make participation as a TEAM collaborator infeasible for any provider, supplier, or other entity on the proposed list of types of TEAM collaborators.

It is necessary that TEAM participants have adequate oversight over sharing arrangements to ensure that all arrangements meet the requirements of this section and provide program integrity protections. Therefore, we propose that the board or other governing body of the TEAM participant have responsibility for overseeing the TEAM participant's' participation in the model, its arrangements with TEAM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the model. Additionally, we propose that the TEAM participant and TEAM collaborator must document this agreement in writing and, as part of the model's monitoring and compliance activities as proposed in (§ 512.590), we propose that this agreement must be made available to CMS upon request.

For purposes of sharing arrangements under the model, we propose at § 512.505 to define activities related to promoting accountability for the quality, cost, and overall care for TEAM beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model as TEAM activities. In addition to the quality of care provided during episodes, we believe the activities that would fall under this proposed definition encompass the totality of activities upon which it would be appropriate for sharing arrangements under the model to be based in order to value the contributions of providers, suppliers, and other entities toward meeting the performance goals of the model. We seek comment on the proposed definition of TEAM activities as an inclusive and comprehensive framework for capturing direct care and care redesign that contribute to performance toward model goals.

We propose that the written agreement memorializing a sharing arrangement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.
- The identities and obligations of the parties, including specified TEAM activities and other services to be performed by the parties under the sharing arrangement.

- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out TEAM activities.
- The financial or economic terms for payment, including the following:

++ Eligibility criteria for a gainsharing payment.

++ Eligibility criteria for an alignment payment.

++ Frequency of gainsharing or alignment payment.

++ Methodology and accounting formula for determining the amount of a gainsharing payment that is solely based on quality of care and the provision of TEAM activities.

++ Methodology and accounting formula for determining the amount of an alignment payment.

Finally, we propose to require that the terms of the sharing arrangement must not induce the TEAM participant, TEAM collaborator, or any employees, contractors, or subcontractors of the TEAM participant or TEAM collaborator to reduce or limit medically necessary services to any beneficiary or restrict the ability of a TEAM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. These requirements are to ensure that the quality of care for beneficiaries is not negatively affected by sharing arrangements under the model.

The proposals for the requirements for sharing arrangements under the model are included in § 512.565. We seek comment on all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(c) Gainsharing Payment and Alignment Payment Conditions and Limitations

We propose several conditions and limitations for gainsharing payments and alignment payments as program integrity protections for the payments to and from TEAM collaborators. We propose to require that gainsharing payments be derived solely from a TEAM participant's reconciliation payment amounts, internal costs savings, or both; that they be distributed on an annual basis, not more than once per calendar year; that they not be a loan, advance payment, or payment for referrals or other business; and that they be clearly identified as a gainsharing payment at the time they are paid.

We believe that gainsharing payment eligibility for TEAM collaborators should be conditioned on two requirements—(1) quality of care criteria; and (2) the provision of TEAM activities. With respect to the first requirement, we propose that to be eligible to receive a gainsharing payment, the TEAM collaborator must meet quality of care criteria during the performance year for which the TEAM participant earned a reconciliation payment amount that comprises the gainsharing payment. We propose that this quality of care criteria will be included in the sharing arrangement and mutually agreed upon by the TEAM participant and TEAM collaborator. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator other than a PGP, NPPGP, or TGP must have directly furnished a billable item or service to a TEAM beneficiary during the same performance year for which the TEAM participant earned a reconciliation payment amount or repayment amount. For purposes of this requirement, we consider a hospital, CAH or post-acute care provider to have ''directly furnished'' a billable service if one of these entities billed for an item or service for a TEAM beneficiary in the performance year for which the TEAM participant earned a reconciliation payment amount or repayment amount. The phrase ''episode'' refers to all Part A and B items and services described in section X.A.3.b.(5) (excluding the items and services described in section X.A.3.b.(5)(a)) of the preamble of this proposed rule that are furnished to a beneficiary described in section X.A.3.b.(5).(b) of the preamble of this proposed rule. During the time period that begins with the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as applicable, and ends on the 30th day of either the date of discharge from the anchor hospitalization or the date of service for the anchor procedure. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for TEAM beneficiaries during an episode for these TEAM collaborators. We believe the provision of direct care is essential to the implementation of effective care redesign, and the requirement provides a safeguard against payments to TEAM collaborators other than a PGP, NPPGP, or TGP that are unrelated to direct care for TEAM beneficiaries during the model's performance year.

We propose to establish similar requirements for PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services. To be eligible to receive a gainsharing payment or required to make an alignment payment for a given performance year, a PGP, NPPGP or TGP must have billed for an item or service that was rendered by one or more members of the PGP, NPPGP or TGP to a TEAM beneficiary during the episode that is attributed to the same performance year for which the TEAM participant earned a reconciliation payment amount or repayment amount. Like the proposal for TEAM collaborators that are not PGPs, these proposals also require a link between the TEAM collaborator that is the PGP, NPPGP or TGP and the provision of items and services to beneficiaries during the episode by PGP, NPPGP or TGP members.

Moreover, we further propose that, because PGPs, NPPGPs and TGPs do not directly furnish items and services to beneficiaries, in order to be eligible to receive a gainsharing payment or be required to make an alignment payment, for a given performance year the PGP, NPPGP or TGP must have contributed to TEAM activities and been clinically involved in the care of beneficiaries during an episode that is attributed to the same performance year for which the TEAM participant earned a reconciliation payment amount or repayment amount that comprises the gainsharing payment.

We propose that the amount of any gainsharing payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of TEAM activities, but ultimately determined that basing the methodology solely on these two elements creates a model safeguard where gainsharing aligns directly with the model goal of quality of care and with TEAM activities. The gainsharing methodology may take into account the amount of such TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators. While we emphasize that financial arrangements may not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among TEAM participants, any TEAM collaborator, any collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator,

or collaboration agent so that their sole purpose is to align the financial incentives of the TEAM participant and TEAM collaborators toward the model, we believe that accounting for the relative amount of TEAM activities by TEAM collaborators in the determination of gainsharing payments does not undermine this objective. Rather, the proposed requirement allows flexibility in the determination of gainsharing payments where the amount of a TEAM collaborator's provision of TEAM activities (including direct care) to beneficiaries during a performance year may contribute to the TEAM participant's reconciliation payment amount that may be available for making a gainsharing payment. Greater contributions of TEAM activities by one TEAM collaborator versus another TEAM collaborator that result in greater differences in the funds available for gainsharing payments may be appropriately valued in the methodology used to make gainsharing payments to those TEAM collaborators in order to reflect these differences in TEAM activities among TEAM collaborators.

However, we do not believe it would be appropriate to allow the selection of TEAM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment to take into account the amount of TEAM activities provided by a potential or actual TEAM collaborator relative to other potential or actual TEAM collaborators because these financial relationships are not to be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, or collaboration agent. Specifically, with respect to the selection of TEAM collaborators or the opportunity to make or receive a gainsharing payment or an alignment payment, we do not believe that the amount of model activities provided by a potential or actual TEAM collaborator relative to other potential or actual TEAM collaborators could be taken into consideration by the TEAM participant without a significant risk that the financial arrangement in those instances could be based directly or indirectly on the volume or value of referrals or business generated by, between or among the parties. Similarly, if the methodology for determining alignment payments was allowed to take into account the amount of TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators there would be a significant risk that the financial arrangement could directly account for the volume or value of referrals or business generated by, between or among the parties and, therefore, we propose that the methodology for determining alignment payments may not directly take into account the volume or value of referrals or business generated by, between or among the parties.

We seek comment on this proposal, where any gainsharing payments must be determined in accordance with a methodology that is based on quality of care and the provision of TEAM activities. We also seek comment on whether the methodology must be based solely on these two elements, or if, alternately, the methodology must be based substantially on these two elements. We seek comment on this proposal for gainsharing payments, where the methodology could take into account the amount of TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators. We are particularly interested in comments about whether this standard would provide sufficient additional flexibility in the gainsharing payment methodology to allow the financial reward of TEAM collaborators commensurate with their level of effort that achieves model goals. In addition, we are interested in comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and ensuring the goals of the model are met.

We propose that for each performance year, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment amount by the TEAM participant must not exceed the amount of the reconciliation payment amount. In accordance with the prior discussion, no entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, or collaboration agent. We propose that a TEAM participant must not make a gainsharing payment to a TEAM collaborator that is subject to any action for noncompliance by CMS or any other federal or state entity or subject to noncompliance with any other federal or state laws or regulations, or for the provision of substandard care to beneficiaries or other integrity problems. Finally, the sharing arrangement must require the TEAM participant to recover any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data. These requirements provide program integrity safeguards for gainsharing under sharing arrangements.

With respect to alignment payments, we propose that alignment payments from a TEAM collaborator to a TEAM participant may be made at any interval that is agreed upon by both parties. Alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of the repayment amount, and cannot be assessed in the absence of a repayment amount. The TEAM participant must not receive any amounts under a sharing arrangement from a TEAM collaborator that are not alignment payments.

We also propose certain limitations on alignment payments that are consistent with the CJR model. For a performance year, the aggregate amount of all alignment payments received by the TEAM participant from all of the TEAM participant's TEAM collaborators must not exceed 50 percent of the repayment amount. Given that the TEAM participant would be responsible for developing and coordinating care redesign strategies in response to its TEAM participation, we believe it is important that the TEAM participant retain a significant portion of its responsibility for repayment amounts. In addition, the aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant for a TEAM collaborator other than an ACO may not be greater than 25 percent of the TEAM participant's repayment amount. The aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant for a TEAM collaborator that is an ACO may not be greater than 50 percent of the TEAM participant's repayment amount.

We seek comment on our proposed aggregate and individual TEAM collaborator limitations on alignment payments.

We propose that all gainsharing payments and any alignment payments must be administered by the TEAM participant in accordance with GAAP and Government Auditing Standards (The Yellow Book). Additionally, we

propose that all gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction. We make this proposal to mitigate the administrative burden that the electronic fund transfer (EFT) requirement would place on the financial arrangements between certain TEAM participants and TEAM collaborators, especially individual physicians and nonphysician practitioners and small PGPs, NPPGPs or TGPs which could discourage participation of those suppliers as TEAM collaborators. We seek comment on the effect of this proposal.

The proposals for the conditions and restrictions on gainsharing payments, alignment payments, and internal cost savings under the model are included in proposed § 512.56. We seek comment about all of the conditions and restrictions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of TEAM are met.

(d) Documentation Requirements

To ensure the integrity of the sharing arrangements, we propose that TEAM participants must meet a variety of documentation requirements for these arrangements. Specifically, the TEAM participant must—

- Document the sharing arrangement contemporaneously with the establishment of the arrangement;
- Maintain accurate current and historical lists of all TEAM collaborators, including TEAM collaborator names and addresses; update such lists on at least a quarterly basis; and publicly report the current and historical lists of TEAM collaborators on a web page on the TEAM participant's website; and
- Maintain and require each TEAM collaborator to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes at a minimum the—

++ Nature of the payment (gainsharing payment or alignment payment);

++ Identity of the parties making and receiving the payment;

++ Date of the payment;

++ Amount of the payment;

++ Date and amount of any recoupment of all or a portion of a TEAM collaborator's gainsharing payment; and

++ Explanation for each recoupment, such as whether the TEAM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment amount, or was based on the submission of false or fraudulent data.

In addition, we propose that the TEAM participant must keep records for all of the following:

- Its process for determining and verifying its potential and current TEAM collaborators' eligibility to participate in Medicare if the TEAM collaborator is a Medicare-enrolled provider or supplier.
- A description of current health information technology, including systems to track reconciliation payment amounts and repayment amounts.
- Its plan to track gainsharing payments and alignment payments.

Finally, we propose that the TEAM participant must retain and provide access to, and must require each TEAM collaborator to retain and provide access to, the required documentation in accordance with section X.A.3.j. of the preamble of this proposed rule and 42 CFR 1001.952(ii).

The proposals for the requirements for documentation of sharing arrangements under the model are included in § 512.565. We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(5) Distribution Arrangements

(a) General

Similar to the CJR model, we propose that certain financial arrangements between TEAM collaborators and other individuals or entities called ''collaboration agents'' be termed ''distribution arrangements.'' A collaboration agent is an individual or entity that is not a TEAM collaborator and that is a PGP, NPPGP, or TGP member that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee. For purposes of the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), we propose that a distribution arrangement is a financial arrangement between a TEAM collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP. Where a payment from a TEAM collaborator to a collaboration agent is made pursuant to a TEAM distribution arrangement, we define that payment as a ''distribution payment.'' A collaboration agent may only make a distribution payment in accordance with a distribution arrangement which complies with the provisions of this proposed model and all other applicable laws and regulations, including the fraud and abuse laws.

Like our proposal for gainsharing payments, we propose that the amount of any distribution arrangements must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities. We considered whether this methodology could substantially, rather than solely, be based on quality of care and the provision of TEAM activities, but ultimately determined that basing the methodology solely on these two elements creates a model safeguard where gainsharing aligns directly with the model goal of quality of care and with TEAM activities.

The proposals for the general provisions for distribution arrangements under the model are included in § 512.568. We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(b) Requirements

We propose several specific requirements for distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between TEAM collaborators and collaboration agents and performance toward TEAM goals. These requirements largely parallel those proposed in section X.A.3.g.(4) Of the preamble of this proposed rule for sharing arrangements and gainsharing payments based on similar reasoning for these two types of arrangements and payments. We propose that all distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

We seek comment on this proposal, where any distribution payments must be determined in accordance with a

methodology that is based on quality of care and the provision of TEAM activities. We also seek comment on whether the methodology must be based solely on these two elements, or if the methodology must be based substantially on these two elements. Additionally, and also like our proposal for gainsharing payments, we propose that the opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, or collaboration agent. We propose more flexible standards for the determination of the amount of distribution payments from PGPs, NPPGPs and TGPs allowing TEAM collaborators and collaboration agents to create tailored distribution payments that supports the individual structure of their arrangement.

We note that for distribution payments made by a PGP to PGP members, by NPPGPs to NPPGP members, or TGPs to TGP members, the requirement that the amount of any distribution payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities may be more limiting in how a PGP, NPPGP or TGP pays its members than is allowed under existing law. However, we believe quality of care is an important facet of episode-based payment models and making this a requirement for distribution payment supports greater emphasis on quality of care improvement in TEAM. Further this is consistent with the BPCI Advanced model that required their NPRA Shared Payments and Partner Distribution Payments to achieve quality performance targets to receive these payments.

We seek comment on this proposal and specifically whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members or a TGP to its members.

Similar to our proposed requirements for sharing arrangements for those TEAM collaborators that furnish or bill for items and services, we propose that a collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a beneficiary during an episode that occurred during the same performance year for which the TEAM participant accrued the internal cost savings or earned a reconciliation payment amount that comprises the gainsharing payment being distributed. We note that all individuals and entities that fall within our proposed definition of collaboration agent may either directly furnish or bill for items and services rendered to beneficiaries. This proposal ensures that, there is the same required relationship between direct care for beneficiaries during a performance year and distribution payment eligibility that we require for gainsharing payment eligibility. We believe this requirement provides a safeguard against payments to collaboration agents that are unrelated to direct care for beneficiaries during the performance year.

We further propose that with respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP or TGP, the total amount of all distribution payments in a performance year must not exceed the amount of the gainsharing payment received by the TEAM collaborator from the TEAM participant for that performance year. Like gainsharing and alignment payments, we propose that all distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The collaboration agent must retain the ability to make decisions in the best interests of the beneficiary, including the selection of devices, supplies, and treatments. Finally, the distribution arrangement must not induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the TEAM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.586, including—

- The relevant written agreements;
- The date and amount of any distribution payment(s);
- The identity of each collaboration agent that received a distribution payment; and
- A description of the methodology and accounting formula for determining the amount of any distribution payment.

We propose that the TEAM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same TEAM participant. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment and distribution payment to PGPs, NPPGPs, TGPs, physicians, and nonphysician practitioners that are solely based on quality of care and the provision of TEAM activities are not exceeded in absolute dollars by a PGP, NPPGP, TGP, physician, or nonphysician practitioner's participation in both a sharing arrangement and distribution arrangement for the care of the same TEAM beneficiaries during the performance year. Allowing both types of arrangements for the same individual or entity for care of the same beneficiary during the performance year could also allow for duplicate counting of the individual or entity's same contribution toward model goals and provision of TEAM activities in the methodologies for both gainsharing and distribution payments, leading to financial gain for the individual or entity that is disproportionate to the contribution toward model goals and provision of TEAM activities by that individual or entity. However, we recognize there could be instances where an individual or entity could have distribution arrangements with multiple TEAM collaborators. For example, a physician may practice with and have reassigned their Medicare billing rights to multiple PGPs, and those PGPs may each be TEAM collaborators. We seek comment on allowing an individual or entity to have distribution arrangements with multiple TEAM collaborators and whether there are additional program integrity safeguards that should be established in those scenarios. Finally, we propose that the TEAM collaborator must retain and provide access to, and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

The proposals for requirements for distribution arrangements under the model are included in § 512.568. We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. In addition, we seek comment on how the regulation of the financial arrangements under this proposal may interact with how these or similar financial arrangements are regulated under the Medicare Shared Savings Program.

(6) Downstream Distribution Arrangements

(a) General

We propose that TEAM allow for certain financial arrangements within an ACO between a PGP and its members. Specifically, we propose that certain financial arrangements between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and other individuals termed ''downstream collaboration agents'' be termed a ''downstream distribution arrangement.'' A downstream distribution arrangement is a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP. A downstream collaboration agent is an individual who is not a TEAM collaborator or a collaboration agent and who is a PGP member, a NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent. Where a payment from a collaboration agent to a downstream collaboration agent is made pursuant to a downstream distribution arrangement, we define that payment as a ''downstream distribution payment.'' A collaboration agent may only make a downstream distribution payment in accordance with a downstream distribution arrangement which complies with the requirements of this section and all other applicable laws and regulations, including the fraud and abuse laws.

We seek comment about all of the provisions set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the TEAM are met.

(b) Requirements

We propose several specific requirements for downstream distribution arrangements as a program integrity safeguard to help ensure that their sole purpose is to create financial alignment between collaboration agents that are PGPs, NPPGPs, or TGPs which are also ACO participants and downstream collaboration agents toward the goals of the TEAM to improve the quality and efficiency of episodes. These requirements largely parallel those proposed for sharing and distribution arrangements at proposed § 512.565 and § 512.568 and gainsharing and distribution payments at proposed § 512.565 and § 512.568 based on similar reasoning for these types of arrangements and payments. We propose that all downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and entered into before care is furnished to TEAM beneficiaries under the downstream distribution arrangement. Furthermore, we propose that participation must be voluntary and without penalty for nonparticipation, and the downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

Like our proposals for gainsharing and distribution payments, we propose that the opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent. We propose the amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a downstream collaboration agent relative to other downstream collaboration agents. We believe that the amount of a downstream collaboration agent's provision of TEAM activities (including direct care) to TEAM beneficiaries during episodes may contribute to the TEAM participant's internal cost savings and reconciliation payment amount that may be available for making a gainsharing payment to the TEAM collaborator that is then shared through a distribution payment to the collaboration agent with which the downstream collaboration agent has a downstream distribution arrangement. Greater contributions of TEAM activities by one downstream collaboration agent versus another downstream collaboration agent that result in different contributions to the distribution payment made to the collaboration agent with which the downstream collaboration agents both have a downstream distribution arrangement may be appropriately valued in the methodology used to make downstream distribution payments to those downstream collaboration agents.

Similar to our proposed requirements for distribution arrangements for those TEAM collaborators that are PGPs, we propose that a downstream collaboration agent is eligible to receive a downstream distribution payment only if the PGP billed for an item or service furnished by the downstream collaboration agent to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount that comprise the gainsharing payment from which the ACO made the distribution payment to the PGP that is an ACO participant. This proposal ensures that there is the same required relationship between direct care for TEAM beneficiaries during episodes and downstream distribution payment eligibility that we require for gainsharing and distribution payment eligibility. We believe this requirement provides a safeguard against payments to downstream collaboration agents that are unrelated to direct care for TEAM beneficiaries during episodes.

We further propose that the total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the collaboration agent (that is, the PGP, NPPGP, or TGP that is an ACO participant) from the ACO that is a TEAM collaborator. Like gainsharing, alignment, and distribution payments, we propose that all downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction. The downstream collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. The distribution arrangement must not induce a downstream collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary or reward the provision of items and services that are medically unnecessary.

We propose that the PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.586, including all of the following:

- The relevant written agreements.
- The date and amount of any downstream distribution payment(s).

- The identity of each downstream collaboration agent that received a downstream distribution payment.
- A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

We propose that the PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP, NPPGP, or TGP member who has a sharing arrangement with a TEAM participant or distribution arrangement with the ACO the PGP, NPPGP, or TGP is a participant in. This proposal ensures that the proposed separate limitations on the total amount of gainsharing payment, distribution payment, and downstream distribution payment to PGP, NPPGP, or TGP members that are solely based on quality of care and the provision of TEAM activities are not exceeded in absolute dollars by a PGP, NPPGP, or TGP member's participation in more than one type of arrangement for the care of the same TEAM beneficiaries during episodes. Allowing more than one arrangement for the same PGP, NPPGP, or TGP member for the care of the same TEAM beneficiaries during episodes could also allow for duplicate counting of the PGP, NPPGP, or TGP member's effort in TEAM activities in the methodologies for the different payments. Finally, we propose that the PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

We seek comment about all of the requirements, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of TEAM are met.

(7) Beneficiary Incentives

We believe it is necessary and appropriate to provide additional flexibilities to TEAM participants for purposes of testing the Model, to give TEAM participants additional access to the tools necessary to improve beneficiaries' quality of care, drive equitable outcomes, and reduce Medicare spending through improved beneficiary care transitions and reduced fragmentation during episodes of care. *TEAM participants* may choose to provide in-kind *patient* engagement incentives to beneficiaries in an episode, which may include but not be limited to items of technology, subject to the following conditions consistent with 42 CFR 510.515.

As discussed in section X.A.3.g.(9) of the preamble of this proposed rule, if the proposed beneficiary incentives are finalized, we expect to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available to protect the beneficiary incentives proposed in this section when the incentives are offered in compliance with the requirements established in the final rule and the conditions for use of the anti-kickback statute safe harbor set out at 42 CFR 1001.952(ii).

As stated previously, TEAM participants may choose to provide in-kind engagement incentives, which may include but not be limited to items of technology, to TEAM beneficiaries in an episode, subject to the following proposed conditions. We propose that the incentive must be provided directly by the TEAM participant or by an agent of the TEAM participant under their direction and control to the TEAM beneficiary during an episode. Additionally, we propose that the item or service provided must be reasonably connected to the TEAM beneficiary's medical care, and be a preventive care item or service or an item of service that advances a clinical goal, as described in section X.A.3.g.(7)(b) of the preamble of this proposed rule, by engaging the TEAM beneficiary in better managing their own health. We seek comment on the proposed conditions for TEAM beneficiary incentives, as outlined in 512.575. Specifically, we seek comment on whether these proposed conditions are reasonable, and whether additional conditions are appropriate to further engage TEAM beneficiaries in their own healthcare management while preventing fraud or abuse.

(a) Technology Provided to a TEAM Beneficiary

In some cases, items or services involving technology may be useful as beneficiary engagement incentives that can advance a clinical goal of TEAM by engaging a beneficiary in managing their health during the 30 days following discharge from the anchor hospitalization or anchor procedure. However, we believe specific enhanced safeguards are necessary for these items and services to prevent abuse, and our proposals are consistent with the CJR model policies (80 FR 73437). Specifically, we propose that items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any TEAM beneficiary in any episode (per episode), and that items or services involving technology provided to a TEAM beneficiary must be the minimum necessary to advance a clinical goal as discussed in this section for a TEAM beneficiary in an episode. We propose additional enhanced requirements for items of technology exceeding $75 in retail value as an additional safeguard against misuse of these items as beneficiary engagement incentives. Specifically, we propose that these items of technology that exceed $75 in retail value remain the property of the TEAM participant and be retrieved from the TEAM beneficiary at the end of the episode. The TEAM participant must document all retrieval attempts, including the ultimate date of retrieval. We understand that TEAM participants may not always be able to retrieve these items after the episode ends, such as when a TEAM beneficiary dies or moves to another geographic area. Therefore, in cases when the item of technology is not able to be retrieved, the TEAM participant must determine why the item was not retrievable and if it was determined that the item was used inappropriately (if it were sold, for example) preventing future beneficiary incentives for that TEAM beneficiary. Following this process, the documentation of diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

Our proposals for enhanced requirements for technology provided to TEAM beneficiaries as beneficiary engagement incentives under TEAM are included in proposed § 512.578. We seek comment on our proposed requirements for beneficiary engagement incentives that involve technology. Additionally, we seek comment on the types of technology that may be useful to advance the goals of the Model. We welcome comment on additional or alternative program integrity safeguards for this type of beneficiary engagement incentive, including whether the financial thresholds proposed in this section are reasonable, necessary, and appropriate.

(b) Clinical Goals of TEAM

As discussed in section X.A.3.b. of the preamble of this proposed rule, the proposed episodes are broadly defined to include most Part A and Part B items and services furnished during episodes of care that extend 30 days following discharge from the anchor hospitalization or anchor procedure that begins the episode. Therefore, we believe that in-kind beneficiary engagement incentives may appropriately be provided for managing acute conditions arising from episodes, as well as chronic conditions if the condition is likely to have been affected

by care during the episode or when substantial services are likely to be provided for the chronic condition during the episode. We are proposing to allow TEAM participants to offer in-kind beneficiary engagement incentives, where such incentives must be closely related to the provision of high-quality care and advance a clinical goal for a TEAM beneficiary and should not serve as inducements for TEAM beneficiaries to seek care from the TEAM participants or other specific suppliers and providers. We propose that beneficiary incentives must advance one of the following clinical goals of TEAM:

- Beneficiary adherence to drug regimens.
- Beneficiary adherence to a care plan.
- Reduction of readmissions and complications resulting from treatment during the episode.
- Management of chronic diseases and conditions that may be affected by treatment for the TEAM clinical condition.

Our proposals for beneficiary engagement incentives are included in § 512.575. We seek comment on our proposed clinical goals of TEAM, as well as whether the advancement of additional or different clinical goals through beneficiary engagement incentives may better advance the overarching goals of TEAM while maintaining appropriate program integrity safeguards.

(c) Documentation of Beneficiary Engagement Incentives

As a program safeguard against misuse of beneficiary engagement incentives under TEAM, we propose that TEAM participants must maintain documentation of items and services furnished as beneficiary engagement incentives that exceed $25 in retail value including items of technology. In addition, we propose to require that the documentation established contemporaneously with the provision of the items and services must include at least the following:

- The date the incentive is provided.
- The incentive and estimated value of the item or service.
- The identity of the beneficiary to whom the item or service was provided.

We further propose that the documentation regarding items of technology exceeding $75 in retail that are required to be retrieved from the beneficiary at the end of an episode must also include contemporaneous documentation of any attempt to retrieve technology. In instances where the item of technology is not able to be retrieved, the TEAM participant must determine why it is not retrievable, and if the item were misappropriated (if it were sold, for example), then further steps must be taken to ensure that TEAM beneficiary does not receive further TEAM beneficiary incentives. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

Finally, we propose that the TEAM participant must retain and provide access to the required documentation in accordance with § 512.586.

Our proposals for the documentation requirements for beneficiary engagement incentives under TEAM are included in proposed§ 512.578(d). We seek comment on our proposed documentation requirements, including whether additional or different documentation requirements may provide better program integrity safeguards.

(8) Enforcement Authority

OIG authority is not limited or restricted by the provisions of the model, including the authority to audit, evaluate, investigate, or inspect the TEAM participant, TEAM collaborators, collaboration agents, downstream collaboration agents, or any other person or entity or their records, data, or information, without limitations. Additionally, no model provisions limit or restrict the authority of any other Government Agency to do the same.

The proposals for enforcement authority under the model are included in § 512.575. We seek comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(9) Fraud and Abuse Waiver and OIG Safe Harbor Authority

Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii) of the Act, and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

For this model and consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Any such waiver would apply solely to TEAM and could differ in scope or design from waivers granted for other programs or models. Thus, notwithstanding any provision of this proposed rule, TEAM participants, TEAM collaborators, collaboration agents, and downstream collaboration agents must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for TEAM.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii) (1) and 42 CFR 1001.952(ii)(2)) is available to protect remuneration exchanged pursuant to certain financial arrangements and patient incentives that may be permitted under the final rule, if issued. Specifically, if the proposed rule is finalized, we expect to determine that the CMS-sponsored models safe harbor will be available to protect the following financial arrangements and incentives: the TEAM sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments with TEAM collaborators and collaboration agents, the downstream distribution arrangements and downstream distribution payments with collaboration agents and downstream collaboration agents, and TEAM beneficiary incentives. At proposed § 512.576, we propose to make the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements available to protect remuneration furnished in the TEAM in the form of sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments, and the downstream distribution arrangement's distribution payments provided that all of the financial arrangements associated with such payment meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), proposed § 512.565, proposed § 512.568, and proposed § 512.570. We considered, but are not proposing, adopting an alternative approach in which the availability of the safe harbor for a specific type of financial arrangement would only be conditioned on compliance with the specific requirements for that type of financial arrangement and the

compliance of the other financial arrangements associated with such payment would not implicate the availability of the safe harbor. For example, we considered, but are not proposing, an alternative proposal making the availability of the safe harbor for sharing arrangement's gainsharing payments only conditioned on compliance with the requirements associated with that type of financial arrangement and not also conditioned on the compliance of a downstream financial arrangement associated with such payment.

We considered not allowing use of the safe harbor provisions. However, we decided that use of the safe harbor will encourage the goals of the model. We believe that a successful model requires integration and coordination among TEAM participants and other health care providers and suppliers. We believe the use of the safe harbor will encourage and improve beneficiary experience of care and coordination of care among providers and suppliers. We also believe these safe harbors offer flexibility for innovation and customization. The safe harbors allow for emerging arrangements that reflect up-to-date understandings in medicine, science, and technology.

We seek comment on this proposal, including that the anti-kickback safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) be available to TEAM participants and TEAM collaborators, collaboration agents, and downstream collaboration agents.

h. Proposed Waivers of Medicare Program Requirements

(1) Overview

We believe it may be necessary and appropriate to provide flexibilities to hospitals participating in TEAM, as well as other providers and suppliers that furnish services to beneficiaries in episodes. The purpose of such flexibilities would be to increase episode quality, decrease episode spending or internal costs, or both of providers and suppliers, resulting in better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in section X.A.2.c. of the preamble of this proposed rule, our previous and current efforts in testing episode payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. As discussed in section X.A.3.a.(3) of the preamble of this proposed rule, we are proposing that TEAM participants participating in Track 1 of this model be eligible for reconciliation payment amounts based on spending and quality performance in PY1. TEAM participants in Track 2 would be eligible for repayment amounts and reconciliation payment amounts starting in PY2, while TEAM participants in Track 3 are eligible for repayment amounts and reconciliation payment amounts starting in PY1. We believe that where TEAM participants bear financial accountability for excess episode spending beyond the reconciliation target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to TEAM beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient inpatient episodes would be the 3-day inpatient hospital stay requirement prior to a covered skilled nursing facility (SNF) stay for beneficiaries who could appropriately be discharged to a SNF after less than a 3-day inpatient hospital stay. This type of waiver was implemented in a range of previous and existing CMS initiatives, including various episode-based payment models and accountable care initiatives.

We welcome comments on possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test. We are especially interested in comments explaining how such waivers could provide providers and suppliers with additional flexibilities that are not permitted under existing Medicare rules to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of TEAM where TEAM participants bear full responsibility for total episode spending.

Specific program rules for which we propose waivers under TEAM to support provider and supplier efforts to increase quality and decrease episode spending and for which we invite comments are included in the sections that follow. We propose that these waivers of program rules would apply to the care of beneficiaries who are in episodes at the time when the waiver is used to bill for a service that is furnished to the beneficiary, even if the episode is later cancelled as described in section X.A.3.b.(5)(e) of the preamble of this proposed rule. Finally, we propose that if a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in TEAM at the time the service was furnished, CMS would recover payment for that service from the provider or supplier who was paid, and require that provider and supplier to repay the beneficiary for any coinsurance previously collected.

(2) Post-Discharge Home Visits and Homebound Requirement

We expect that the broadly defined episodes with a duration of 30 days following an anchor hospitalization or anchor procedure discharge as we propose in section X.A.3.b. of the preamble of this proposed rule would result in TEAM participants redesigning care by increasing care coordination and management of beneficiaries following discharge from an anchor hospitalization or anchor procedure. This result would require TEAM participants to pay close attention to any underlying medical conditions that could be affected by the anchor hospitalization or anchor procedure and improving coordination of care across care settings and providers. Beneficiaries may have mobility limitations during certain episodes

following discharge to their home or place of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Increasing beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or PAC setting would be important to high quality episode care. Evidence exists to support the use of home visits among Medicare beneficiaries in improving clinical outcomes and reducing readmissions following hospital discharge.[700] [701] In addition, we believe the financial incentives in TEAM would encourage hospitals to closely examine the most appropriate PAC settings for beneficiaries, taking into consideration beneficiary choice and location of beneficiary home or place of residence, so that the clinically appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization or anchor procedure. We expect that all these considerations would lead to greater interest on the part of hospitals and other providers and suppliers caring for TEAM beneficiaries in furnishing services to beneficiaries in their home or place of residence. Such services could include visits by licensed clinicians other than physicians and nonphysician practitioners.

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''homebound''. Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such services are or were required because the individual is or was ''confined to the home'' and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100–02); Chapter 7, ''Home Health Services,'' Section 30.1.1, ''Patient Confined to the Home.''

We considered whether a waiver of the homebound requirement would be appropriate under TEAM. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we are not proposing to waive the homebound requirement under TEAM for several reasons. Based on the typical clinical course of beneficiaries after certain surgical procedures, we believe that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalization or following discharge to their home or place of residence from a SNF that furnished PAC services immediately following the hospital discharge, so they could receive medically necessary home health services under existing program rules. Home health agencies (HHAs) are paid a national, standardized 30-day period payment rate if a period of care meets a certain threshold of home health visits. 30-day periods of care that do not meet the visit threshold are paid a per-visit payment rate for the discipline providing care. For those TEAM beneficiaries who could benefit from home visits by a licensed clinician for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment but who are not homebound, we do not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as BPCI Advanced and CJR, we have not waived the homebound requirement for home health services.

In the BPCI Advanced and CJR models, we have provided a waiver of the ''incident to'' rule to allow a physician or nonphysician practitioner participating in care redesign under a participating provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The ''incident to'' rules are set forth in § 410.26(b)(5), which requires services and supplies furnished incident to the service of a physician or other practitioner must be provided under the direct supervision (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In the BPCI Advanced and CJR models, the waiver is available only for services that are furnished by licensed clinical staff under the general supervision (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service. While the services may be furnished by licensed clinical staff, they must be billed by the physician (or other practitioner) or participant to which the supervising physician has reassigned their billing rights in accordance with CMS instructions using a Healthcare Common Procedures Coding System (HCPCS) G-code created by CMS

[700] Nabagiez, J.P., Shariff, M.A., Khan, M.A., Molloy, W.J., & McGinn, J.T. (2013). Physician assistant home visit program to reduce hospital readmissions. The Journal of Thoracic and Cardiovascular Surgery, 145(1), 225–233. *https://doi.org/10.1016/j.jtcvs.2012.09.047.*

[701] Hall, M.L., Esposito, G., Pekmezaris, R., Lesser, M., Moravick, D., Jahn, L., Blenderman, R., Akerman, M., Nouryan, C., & Hartman, A.R. (2014). Cardiac surgery nurse practitioner home visits prevent coronary artery bypass graft readmissions. The Annals of Thoracic Surgery, 97(5), 1488–1495. *https://doi.org/10.1016/j.athoracsur.2013.12.049.*

specifically for the BPCI Advanced or CJR model. In the case of the incident to waiver under BPCI Advanced, the waiver allows physician and nonphysician practitioners to furnish the services up to 13 home visits during each 90-day clinical episode. In the case of the incident to waiver under CJR, the waiver allows physician and nonphysician practitioners to furnish the services up to 9 home visits during each 90-day clinical episode. All other Medicare coverage and payment criteria must be met for both BPCI Advanced and CJR models.

We considered waiving the ''incident to'' rule set forth in § 410.26(b)(5) for TEAM, similar to the BPCI Advanced and CJR models, however, we reviewed this specific waiver utilization and found that there was very low uptake in these models. While waiving the ''incident to'' rule set forth in § 410.26(b)(5) could be beneficial in furnishing services to beneficiaries in their home or place of residence, we believe there has been a greater shift towards telemedicine as a modality for post-discharge follow-up, especially after the COVID–19 public health emergency which drove greater adoption and standard practice of telehealth services. Evidence suggests that telemedicine post-discharge visits were effective, safe, and did not negatively affect health care utilization as compared to in-person visits.[702] [703] For these reasons, we are not proposing to waive the ''incident to'' rule set forth in § 410.26(b)(5) for TEAM, but we seek comment if we should waive the ''incident to'' rule set forth in § 410.26(b)(5), if we should consider modifications or alternatives to this waiver, and how we could make this waiver beneficial to TEAM participants and beneficiaries.

(3) Telehealth

As discussed in the previous section, we expect that the proposed TEAM design features would lead to greater interest on the part of hospitals and other providers and suppliers caring for TEAM beneficiaries in furnishing services to beneficiaries in their home or place of residence, including physicians' professional services. TEAM would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization or anchor procedures. Given that we are not waiving the ''incident to'' rule set forth in § 410.26(b)(5) for TEAM, we understand that TEAM participants may still want to engage physicians in furnishing timely visits to homebound or non-homebound TEAM beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, clinicians furnishing home health services, or licensed clinicians furnishing post-discharge home visits, while physicians committed to TEAM care redesign may not be able to revise their practice patterns to meet this home visit need for TEAM beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. Generally, for Medicare payment to be made for telehealth services under the Medicare Physician Fee Schedule several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS website at *https://www.cms.gov/medicare/coverage/telehealth/list-services.* Under section 1834(m)(4)(F)(ii) of the Act, CMS has an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests the benefits of telehealth technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters to increase access to care, especially in rural or underserved areas.[704] In these cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We note that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode-based payment models, such as the BPCI Advanced and CJR models, participants were permitted to use telehealth waivers that applied to two provisions:

- CMS waived the geographic site requirements under 1834(m)(4)(C)(i)(I) through (III) of the Act which allowed telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements.
- CMS waived the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act which allowed the eligible telehealth individual to not be in an originating site when the otherwise eligible individual is receiving telehealth services in their home or place of residence.

These telehealth waivers allowed providers and suppliers furnishing

[702] Harkey, K., Kaiser, N., Zhao, J., Gutnik, B., Kelz, R.R., Matthews, B.D., & Reinke, C.E. (2023). Utilization of telemedicine to provide post-discharge care: A comparison of pre-pandemic vs. pandemic care. The American Journal of Surgery, 226(2), 163–169. *https://doi.org/10.1016/j.amjsurg.2023.03.007.*

[703] Grauer, A., Cornelius, T., Abdalla, M., Moise, N., Kronish, I.M., & Ye, S. (2023). Impact of early telemedicine follow-up on 30-Day hospital readmissions. PLOS ONE, 18(5), e0282081. *https://doi.org/10.1371/journal.pone.0282081.*

[704] Gajarawala, S.N., & Pelkowski, J.N. (2021). Telehealth benefits and barriers. The Journal for Nurse Practitioners, 17(2), 218–221. *https://doi.org/10.1016/j.nurpra.2020.09.013.*

services to model beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and allowed the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. We believe similar telehealth waivers would be essential to maximize the opportunity to improve the quality of care and efficiency for episodes of care in TEAM.

Specifically, like the telehealth waivers in the BPCI Advanced and CJR models, we propose to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode to be furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim that is not excluded from the proposed episode definition (see section X.A.3.b. of the preamble of this proposed rule) could be furnished to a TEAM beneficiary, regardless of the beneficiary's geographic location. Under TEAM, this waiver would support care coordination and increasing timely access to high quality care for all TEAM beneficiaries, regardless of geography. Additionally, we propose for TEAM waiving the originating site requirements of section 1834(m)(4)(C)(ii)(I)–(VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we propose to waive the requirement only when telehealth services are being furnished in the TEAM beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services that is not excluded from the proposed episode definition (see section X.A.3.b.(5)(a) of the preamble of this proposed rule) could be furnished to a TEAM beneficiary in their home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payment for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, we do not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is unspecified. In order to create a mechanism to report E/M services accurately, the BPCI Advanced and CJR models created specific sets of HCPCS G-codes to describe the E/M services furnished to the model beneficiaries in their homes via telehealth. Similarly for TEAM, we propose to create a specific set of nine HCPCS G-codes to describe the E/M services furnished to TEAM beneficiaries in their homes via telehealth. If the proposed TEAM is finalized, we would specify the precise G-code created for TEAM and share them to TEAM participants prior to the first performance year.

Among the existing E/M visit services, we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we propose to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we propose to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, see Table FF–A 10, for CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits. For example, the proposed G- code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history;
- An expanded problem focused examination;
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology.

TABLE X.A.-10 – PROPOSED TEAM TELEHEALTH WAIVER G-CODE CROSSWALK

TEAM G-Code (used for illustrative purposes. Specific G-codes will be created if TEAM is finalized)	Short Descriptor	Corresponding Office/Outpatient E/M CPT Code
GXX01	Remote E/M new pt 10mins	99201
GXX02	Remote E/M new pt 20mins	99202
GXX03	Remote E/M new pt 30 mins	99203
GXX04	Remote E/M new pt 45mins	99204
GXX05	Remote E/M new pt 60mins	99205
GXX12	Remote E/M est. pt 10mins	99212
GXX13	Remote E/M est. pt 15mins	99213
GXX14	Remote E/M est. pt 25mins	99214
GXX15	Remote E/M est. pt 40mins	99215

We note that we are not proposing a G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other qualified health professional.

We propose to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we propose to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, we believe that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and malpractice risk to marginal levels. Therefore, we propose to adopt work and malpractice (MP) RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and malpractice liabilities when conducting a visit via telehealth are comparable to the office visit. We would include final RVUs under the CY 2026 Medicare Physician Fee Schedule for PY 1. Additionally, we propose to update these values each performance year to correspond to final values established under the Medicare Physician Fee Schedule.

We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of TEAM. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the PFS. For the lower level visits, levels 1 through 3 for new and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary medical staff to be available in the patient's home. We anticipate these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We do not propose to include PE RVUs for these services, since we do not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the Medicare Physician Fee Schedule. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit in order for the complete service to be furnished. We believe it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for TEAM beneficiaries in episodes without licensed clinical staff support in the home.

We have considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to TEAM beneficiaries in the home via telehealth, however, we do not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we propose to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We note that because the services described by the proposed G-codes, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also note that

because these home telehealth services are E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

Under TEAM, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

With respect to home health services paid under the home health prospective payment system (HH PPS), we emphasize that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers cannot be furnished for TEAM beneficiaries who are in a home health episode because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, can be furnished for TEAM beneficiaries who are in a home health episode. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed nonphysician practitioner (NPP) working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we are not proposing that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the TEAM beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth is used to meet the requirement for home health certification, the usual Medicare telehealth rules apply with respect to geography and eligibility of the originating site. We expect that this policy would not limit TEAM beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during an episode will have had a face-to- face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a post-acute facility stay prior to discharge directly to home health services.

Under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a TEAM beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished pursuant to the telehealth waivers only during the episode.

We plan to monitor patterns of utilization of telehealth services under TEAM to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. We plan to specifically monitor the distribution of new telehealth home visits that we are proposing, as we anticipate greater use of lower level visits. Given our concern that auxiliary licensed clinical staff be present for level 4 and 5 visits, we will monitor our proposed requirement that these visits be billed on the same claim with the same date of service as a home nursing visit, during a period authorized home health care, or that the physician document the presence of auxiliary licensed clinical staff in the home or an explanation as to the specific circumstances precluding the need for auxiliary staff for the specific visit. We seek comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

(4) 3-Day SNF Rule

Pursuant to section 1861(i) of the Act, a beneficiary must have a prior inpatient hospital stays of no fewer than 3 consecutive days to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived for Medicare SNF coverage under other episode payment models, including the BPCI Advanced the CJR models. Model participants that elect to use the waiver can discharge model beneficiaries in fewer than 3 days from an anchor hospital stay or anchor procedure (in the case of the CJR model) to a SNF, where services are covered under Medicare Part A if all other coverage requirements for such services are satisfied.

Episode-based payment models like BPCI Advanced and CJR have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. These model participants considering the early discharge of a beneficiary pursuant to the waiver must evaluate whether early discharge to a SNF is clinically-appropriate and SNF services are medically necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency.

Because of the potential benefits we see for TEAM participants, their provider partners, and beneficiaries, we propose to waive the SNF 3-day rule for coverage of a SNF stay following the

anchor hospitalization or anchor procedure under TEAM. We propose to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in TEAM. We believe this waiver is necessary to the model test so that TEAM participants can redesign care throughout the episode continuum of care extending to 30 days post-discharge from the anchor hospital stay or anchor procedure to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to TEAM beneficiaries in all performance years of the model. Further, to ensure protection to TEAM beneficiary safety and optimize health outcomes, we propose to require that TEAM participants may only discharge a TEAM beneficiary under this proposed waiver of the SNF 3-day rule to a SNF rated an overall of three stars or better by CMS based on information publicly available at the time of hospital discharge from an anchor hospital stay or anchor procedure. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare website gives each SNF an overall rating of between 1 and 5 stars.[705] Those SNFs with 5 stars are considered to have much above average quality, and SNFs with 1 star are considered to have quality much below average. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization or anchor procedure initiating an episode, especially if that discharge occurs after fewer than 3 days in the hospital. Because of the potential greater risks following early inpatient hospital discharge, we believe it is appropriate that all TEAM beneficiaries discharged from the TEAM participant to a SNF in fewer than 3 days be admitted to a SNF that has demonstrated that it can provide quality care to patients with significant unresolved post- surgical symptoms and problems. We believe such a SNF would need to provide care of at least average overall quality, which would be represented by an overall SNF 3-star or better rating.

Thus, the TEAM participant must discharge the beneficiary to a SNF that is qualified under the SNF 3-day rule waiver. We are proposing that to be qualified under the SNF 3-day rule waiver a SNF must be included in the most recent calendar year quarter Five-Star Quality Rating System listing for SNFs on the Nursing Home Compare website for the date of the beneficiary's admission to the SNF. The qualified SNF must be rated an overall 3 stars or better for at least 7 of the 12 months based on a review of the most recent rolling 12 months of overall star ratings. We propose to post on the CMS website the list of qualified SNFs in advance of the calendar quarter.

We recognize that there may be instances where a TEAM participant would like to use the 3-day SNF rule waiver, but the TEAM beneficiary receives inpatient PAC through swing bed arrangements in a hospital or Critical Access Hospital (CAH), as designated in § 485.606 of this chapter, which is not subject to the Five-Star Quality Rating System. For example, a TEAM beneficiary located in a rural area may wish to receive PAC care closer to their home but there are no qualified SNFs in their area. Allowing TEAM participants to use the 3-day SNF rule waiver for hospitals and CAHs operating under swing bed agreements may support beneficiary freedom of choice and provide greater flexibility to TEAM participants for their care coordination efforts. This approach is consistent with the Shared Savings Program, which offers a similar 3-day SNF rule waiver and allows their ACOs to partner with hospitals and CAHs to with swing bed arrangements to utilize the waiver. Therefore, we seek comment on whether we should allow TEAM participants to use hospitals and CAHs operating under swing bed agreements for the 3-day SNF rule waiver and what beneficiary protections we should include since the Five-Star Quality Rating System would not apply.

We plan to monitor patterns of SNF utilization under the TEAM, particularly with respect to hospital discharge in fewer than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering. We seek comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as 3 stars or better following discharge from the anchor hospitalization or anchor procedures for episodes in TEAM.

(a) Additional Beneficiary Protections Under the SNF 3-Day Stay Rule Waiver

We believe that it will be necessary to propose beneficiary protections against financial liability in addition to the beneficiary protections discussed elsewhere in this proposed rule. Specifically, we believe it is important to discern whether a waiver applies to SNF services furnished to a particular beneficiary to ensure compliance with the conditions of the waiver and improve our ability to monitor waivers for misuse.

In considering additional beneficiary protections that may be necessary to ensure proper use of SNF 3-day rule waiver under the TEAM, we note that there are existing, well-established payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act that include protections for beneficiaries from liability for certain non-covered SNF charges. These existing payment and coverage policies for SNF services continue to apply under the TEAM, including SNF services furnished pursuant to the SNF 3-day waiver. (For example, see section 70 in the Medicare Claims Processing Manual, Chapter 30—Financial Liability Protections on the CMS website at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c30.pdf*; and Medicare Coverage of Skilled Nursing Facility Care *https://www.medicare.gov/coverage/skilled-nursing-facility-snf-care*; Medicare Benefit Policy Manual, Chapter 8—Coverage of Extended Care (SNF) Services Under Hospital Insurance at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c08pdf.pdf*). In general, CMS requires that the SNF inform a beneficiary in writing about services and fees before the beneficiary is discharged to the SNF (§ 483.10(b)(6)); the beneficiary cannot be charged by the SNF for items or services that were not requested (§ 483.10(c)(8)(iii)(A)); a beneficiary cannot be required to request extra services as a condition of continued stay (§ 483.10(c)(8)(iii)(B)); and the SNF must inform a beneficiary that requests an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be (§ 483.10(c)(8)(iii)(C)). (See also section 6 of Medicare Coverage of Skilled

[705] *https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome.*

Nursing Facility Care at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c06.pdf.*)

As we discussed in the CJR final rule (80 FR 73454 through 73460), commenters expressed concern regarding the lag between a CJR beneficiary's Medicare coverage or eligibility status change and a TEAM participant's awareness of that change. There may be cases in which a SNF waiver is used by a TEAM participant because the TEAM participant believes that the beneficiary meets the inclusion criteria, based on the information available to the hospital and SNF at the time of the beneficiary's admission to the SNF, but in fact the beneficiary's Medicare coverage has changed and the hospital was unaware of it based on available information. We recognize that despite good faith efforts by TEAM participants and SNFs to determine a beneficiary's Medicare status for the model, it may occur that a beneficiary is not eligible to be included in the TEAM at the time the SNF waiver is used. In these cases, we will cover services furnished under the waiver when the information available to the provider at the time the services under the waiver were furnished indicated that the beneficiary was included in the model.

Based on our experience with SNF 3-day rule waiver, including the CJR model, we believe there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for the TEAM. Specifically, we are concerned about potential beneficiary financial liability for non-covered Part A SNF services that might be directly related to use of the SNF 3-day waiver under the TEAM. We are concerned that there could be scenarios where a beneficiary could be charged for non-covered SNF services that were a result of a TEAM participant's inappropriate use of the SNF waiver. Specifically, we are concerned that a beneficiary could be charged for non-covered SNF services if a TEAM participant discharges a beneficiary to a SNF that does not meet the quality requirement (3 stars or higher in 7 of the last 12 months), and payment for SNF services is denied for lack of a qualifying inpatient hospital stay. We recognize that requiring a discharge planning notice would help mitigate concerns about beneficiaries' potential financial liability for non-covered services. Nevertheless, we are concerned that in this scenario, once the claim is rejected, the beneficiary may not be protected from financial liability under existing Medicare rules because the waiver would not be available, and the beneficiary would not have had a qualifying inpatient hospital stay. Thus, the TEAM beneficiary could be charged by the SNF for non-covered SNF services that were a result of an inappropriate attempt to use the waiver. In this scenario, Medicare would deny payment of the SNF claim, and the beneficiary could potentially be charged by the SNF for these non-covered SNF services, potentially subjecting such beneficiaries to significant financial liability. In this circumstance, we assume the TEAM participant's intent was to rely upon the SNF 3-day waiver, but the waiver requirements were not met. We believe that in this scenario, the rejection of the claim could easily have been avoided if the hospital had confirmed that the requirements for use of the SNF 3-day waiver were satisfied or if the beneficiary had been provided the discharge planning notice and elected to go to a SNF that met the quality requirement.

The CJR model (82 FR 180) addressed beneficiary liability financial concerns for non- covered SNF services related to the waiver by generally placing the risk on the participant hospital and we believe it is appropriate to propose a similar policy for TEAM. CJR participant hospitals are generally held financially responsible for misusing the waiver in situations where waiver requirements are not met, because participant hospitals are required to be aware of the 3-day waiver requirements. Participant hospitals are the entities financially responsible for episode spending under the model and will make the decision as to whether it is appropriate to discharge a beneficiary without a 3-day stay. In addition, the requirements for use of the SNF waiver are clearly laid out in the CJR final rule (80 FR 73273). CMS posts on the public website a list of qualifying SNFs (those with a 3-star or higher rating for 7 of the last 12 months). CJR participant hospitals are required to consult the published list of SNFs prior to utilizing the SNF 3-day rule waiver.

For participant hospitals that provide a beneficiary with the discharge planning notice, the hospital would not have financial liability for non-covered SNF services that result from inapplicability of the waiver. In other words, when the participant hospital has discharged a beneficiary to a SNF that does not qualify under the conditions of the waiver, and has not provided the required discharge planning notice so that the beneficiary is aware that he or she is accepting financial liability for non-covered SNF services as a result of not having a qualifying inpatient stay, the ultimate responsibility and financial liability for the non-covered SNF stay rests with the participant hospital. For this reason, we are proposing to align with the CJR model policy and require TEAM participants to keep a record of discharge planning notice distribution to TEAM beneficiaries. We will monitor TEAM participants' use of discharge planning notices to assess the potential for their misuse.

To protect TEAM beneficiaries from being charged for non-covered SNF charges in instances when the waiver was used inappropriately, and similar to the CJR model (82 FR 180), we are proposing to add certain beneficiary protection requirements that would apply for SNF services that would otherwise have been covered except for lack of a qualifying hospital stay. Specifically, we propose that if a TEAM participant discharges a beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the TEAM SNF 3-Day Rule waiver quality requirements as of the date of admission to the SNF, the TEAM participant will be financially liable for the SNF stay if no discharge planning notice is provided to the beneficiary, alerting them of potential financial liability. If the TEAM participant provides a discharge planning notice then the TEAM participant will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. In cases where the TEAM participant provides a discharge planning notice and the beneficiary chooses to obtain care from a non- qualified SNF without a qualifying inpatient stay, the beneficiary assumes financial liability for services furnished (except those that are covered by Medicare Part B during a non-covered inpatient SNF stay).

In the event a TEAM beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the TEAM participant has failed to provide a discharge planning notice, we propose that CMS apply the following rules:

- CMS shall make no payment to the SNF for such services.
- The SNF shall not charge the beneficiary for the expenses incurred for such services; and the SNF shall return to the beneficiary any monies collected for such services.
- The hospital shall be responsible for the cost of the uncovered SNF stay.

We seek comment on these proposals. Specifically, we seek comment on

whether it is reasonable to—(1) cover services furnished under the SNF waiver based on TEAM participant knowledge of beneficiary eligibility for the TEAM as determined by Medicare coverage status at the time the services under the waiver were furnished; and (2) to hold the TEAM participant financially responsible for rejected SNF claims if a TEAM beneficiary is discharged to a SNF without a qualifying 3-day inpatient stay, but the SNF is not on the qualified list as of the date of admission to the SNF, and the TEAM participant has failed to provide a discharge planning notice. Finally, we seek comment on any other related issues that we should consider in connection with these proposals to protect beneficiaries from significant financial liability for non-covered SNF services related to the waiver of the SNF 3-day rule under the proposed TEAM. We may address those issues through future notice and comment rulemaking.

i. Monitoring and Beneficiary Protection

(1) Overview

We are proposing the TEAM as we believe it is an opportunity to improve the quality of care and that the policies of the model support making care more easily accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. For example, under this model we are proposing certain waivers which would offer TEAM participants additional flexibilities with respect to furnishing telehealth services and care in SNFs, as discussed in section X.A.3.h. of the preamble of this proposed rule. We believe that this model will improve beneficiary access and outcomes. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We direct readers to sections X.A.3.d.(5) of the preamble of this proposed rule for discussion of the methodology for calculating the reconciliation payment amount or repayment amount to determine the cost and quality performance utilized for this model. We believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care under the TEAM. However, because the TEAM is designed to promote care delivery efficiencies for episodes, providers may seek greater control over the continuum of care and, in some cases, could attempt to direct beneficiaries into care pathways that save money at the expense of beneficiary choice or even beneficiary outcomes. As such, we acknowledge that some additional safeguards may be necessary under the TEAM for program integrity purposes as providers are simultaneously seeking opportunities to decrease costs and utilization. We believe that it is important to consider any possibility of adverse consequences to patients and to ensure that sufficient controls are in place to protect Medicare beneficiaries in episodes under the TEAM.

(2) Beneficiary Choice and Notification

Because we have proposed that hospitals in selected geographic areas would be required to participate in the model, individual beneficiaries would not be able to opt out of the TEAM when they receive care from a TEAM participant in the model. We do not believe that it is consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, and we do not expect it in any way impact beneficiary decisions. Moreover, we do not believe that an ability to opt out of a payment system is a critical factor in upholding beneficiary choice if other safeguards are in place given that this model does not increase beneficiary cost-sharing. However, a beneficiary is not precluded from seeking care from providers or suppliers who do not participate in TEAM. We do believe that full notification and disclosure of the payment model and its possible implications is critical for beneficiary understanding and protection. It is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for beneficiaries to know that they can raise any concerns with their clinicians, with 1–800–Medicare, or with their local Quality Improvement Organizations (QIOs).

This proposed payment model would not limit a beneficiary's ability to choose among Medicare providers or limit Medicare's coverage of items and services available to the beneficiary. Beneficiaries may continue to choose any Medicare participating provider, or any provider who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. The proposed model would allow TEAM participants to enter into TEAM sharing arrangements, as proposed in section X.A.3.g.(4) of the preamble of this proposed rule, with certain providers and these preferred providers may be recommended to beneficiaries as long as those recommendations are made within the constraints of current law. However, TEAM Participants may not limit beneficiaries to a preferred or recommended providers list that is not compliant with restrictions existing under current statutes and regulations.

Moreover, TEAM participants may not charge any TEAM collaborator, as proposed in section X.A.3.g.(3) of the preamble of this proposed rule, a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers, including surgeons, hospitals, post-acute care or any other providers or suppliers. Moreover, as TEAM participants redesign care pathways, it may be difficult for providers to sort individuals based on health care insurance and to treat them differently. We anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. We anticipate this broader care delivery impact to all patients may further promote consistent treatment of all beneficiaries.

We believe that beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid. We believe that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should clearly specify any providers, suppliers, and ACOs holding a sharing arrangement with the TEAM participant should be identified to the beneficiary as a ''financial partner of the hospital for the purposes of participation in TEAM.'' These policies seek to enhance beneficiaries' understanding of their care, improve their ability to share in the decision-making, and ensure that they have the opportunity to consider competing benefits even as they are presented with cost-saving recommendations. We believe that appropriate beneficiary notification should do all of the following:

- Explain the model and how it will or will not impact the beneficiary's care.

- Inform patients that they retain freedom of choice to choose providers and services.
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to care-givers to their Blue Button® electronic health information.
- Explain that TEAM participants may receive beneficiary-identifiable claims data.
- Advise patients that all standard Medicare beneficiary protections remain in place, including the ability to report concerns of substandard care to QIOs and 1–800–MEDICARE.
- Provide a list of the providers, suppliers, and ACOs with whom the TEAM participant has a sharing arrangement. We recognize an exhaustive list of providers, suppliers, and ACOs may lengthen the beneficiary notification unnecessarily, therefore this requirement may be fulfilled by the TEAM participant including in the beneficiary notification a web address where beneficiaries may access the list.

After carefully considering the appropriate timing and circumstances for the necessary beneficiary notification, we are proposing that TEAM participants must require all ACOs, providers, and suppliers who execute a Sharing Arrangement with a TEAM participant to share beneficiary notification materials, to be developed or approved by CMS, that detail this proposed payment model with the beneficiary prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure for a Medicare FFS patient who would be included under the model. TEAM participants must require this notification as a condition of any Sharing Arrangement. Where a TEAM participant does not have Sharing Arrangements with providers or suppliers that furnish services to beneficiaries during an episode, or where the anchor hospitalization or anchor procedure for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a Sharing Arrangement, the beneficiary notification materials must be provided to the beneficiary by the TEAM participant. The purpose of this proposed policy is to ensure that all TEAM beneficiaries receive the beneficiary notification materials, and that they receive such materials as early as possible but no later than discharge from the hospital or hospital outpatient department. We believe that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the model and its potential impact on their care.

In addition, we propose at § 512.582(b)(2) requiring that TEAM participants must require every TEAM collaborator to provide written notice, to be developed by CMS, to applicable TEAM beneficiaries of the existence of its sharing arrangement with the TEAM participant and the basic quality and payment incentives under the model. We propose that the notice must be provided no later than the time at which the beneficiary first receives an item or service from the TEAM collaborator during an episode. We recognize that due to the patient's condition, it may not be feasible to provide notification at such time, in which case the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. We note that beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care. However, we also considered that this information might be best provided by hospitals at the point of admission for all beneficiaries, as hospitals provide other information concerning patient rights and responsibilities at that time. We invite comment on ways in which the timing and source of beneficiary notification could best serve the needs of beneficiaries without creating unnecessary administrative work for providers and suppliers. We believe that this notification is an important safeguard to help ensure that beneficiaries in the model receive all medically necessary services, but it is also an important clinical opportunity to better engage beneficiaries in defining their goals and preferences as they share in the planning of their care.

(3) Monitoring for Access to Care

Given that TEAM participants would receive a reconciliation payment when they are able to meet certain cost and quality performance thresholds, they could have an incentive to avoid complex, high-cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from TEAM participants—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are potentially being systematically excluded. We will publish these data as part of the model evaluation to promote transparency and an understanding of the model's effects. We also propose to continue to review and audit hospitals if we have reason to believe that they are compromising beneficiary access to care. For example, we may audit a hospital or conduct additional claims analyses where initial claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in surgical rates for procedures included in TEAM. We seek comment on our proposals to monitor TEAM participants at § 512.584.

(4) Monitoring for Quality of Care

As we noted previously, in any payment system that promotes efficiencies of care delivery, there may be opportunities to direct patients away from more expensive services at the expense of outcomes and quality. We believe that professionalism, the quality measures in the model, and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care in the inpatient setting, outpatient setting, and in post-acute care settings during the 30 days post- discharge. Accordingly, we believe that the potential for the denial of medically necessary care within the TEAM will not be greater than that which currently exists under IPPS. However, we also believe that we have the authority and responsibility to audit the medical records and claims of participating hospitals and their TEAM collaborators in order to ensure that beneficiaries receive medically necessary services. Similarly, at § 512.590, we propose to monitor arrangements between TEAM participants and their TEAM collaborators to ensure that such arrangements do not result in the denial of medically necessary care or other program or patient abuse. We invite public comment on these proposals and on whether there are elements of the TEAM that would require additional beneficiary protection for the appropriate delivery of inpatient care, and if so, what types of monitoring or safeguards would be most appropriate.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. Therefore, we are proposing at § 512.582(a)(3) to require that TEAM participants must, as part of discharge planning, account for potential financial bias by providing TEAM beneficiaries with a complete list of all available post-acute care options in the Medicare program, including HHAs, SNFs, IRFs, or LTCHs, in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). This list

should also indicate whether the TEAM participant has a sharing arrangement with the post-acute care provider. We expect that the treating surgeons or other treating practitioners, as applicable, will continue to identify and discuss all medically appropriate options with the beneficiary, and that hospitals will discuss the various facilities and providers who are available to meet the clinically identified needs. These proposed requirements for TEAM participants would supplement the existing discharge planning requirements under the hospital Conditions of Participation. We also specifically note that neither the Conditions of Participation nor this proposed transparency requirement preclude hospitals from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in this model. We invite comment on this proposal, including additional opportunities to ensure high quality care.

(5) Monitoring for Delayed Care

We believe the proposed TEAM would incent TEAM participants to create efficiencies in the delivery of care within a 30-day episode following an acute clinical event. Theoretically, the proposed TEAM also could create incentives for TEAM participants or their TEAM collaborators to delay services until after such 30-day window has closed. Consistent with the CJR model, we believe that existing Medicare safeguards are sufficient to protect beneficiaries in the TEAM.

First, our experience with other episode-based payment models such as the BPCI Advanced model has shown that providers focus first on appropriate care and then on efficiencies only as obtainable in the setting of appropriate care. We believe that a 30-day post-discharge episode is sufficient to minimize the risk that TEAM participants and their TEAM collaborators would compromise services furnished in relation to a beneficiary's care. While we recognize that ongoing care for underlying conditions may be required after the 30-day episode, we believe that TEAM participants and other providers and suppliers would be unlikely to postpone key services beyond a 30-day period because the consequences of delaying care beyond such episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the proposed TEAM. As with the CJR model, we propose as part of the reconciliation process (see section X.A.3.d.(5)(i) of the preamble of this proposed rule) that TEAM participants would be financially accountable for certain post- episode payments occurring in the 30 days after conclusion of the episode. We believe that including such a payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, we believe the data collection and calculations used to determine such adjustment would provide a mechanism to check whether providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as such measures are used to monitor and influence clinical care at the institutional level.

We invite public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and ensuring compliance as well as on other methods to ensure that beneficiaries receive high quality, clinically appropriate care.

j. Access to Records and Record Retention

By virtue of their participation in an CMS Innovation Center model, TEAM participants and TEAM collaborators may receive model-specific payments, access to payment rule waivers, or some other model-specific flexibility. Therefore, we believe that CMS's ability to audit, inspect, investigate, and evaluate records and other materials related to participation in CMS Innovation Center models is necessary and appropriate. There is a need for CMS to be able to audit, inspect, investigate, and evaluate records and materials related to participation in CMS Innovation Center models to allow us to ensure that TEAM participants are not denying or limiting the coverage or provision of benefits for beneficiaries as part of their participation in the CMS Innovation Center model. We propose at § 512.505 to define ''model-specific payment'' to mean a payment made by CMS only to TEAM participants, under the terms of the CMS Innovation Center model that is not applicable to any other providers or suppliers; the term ''model-specific payment'' would include, unless otherwise specified, the reconciliation payment, described in section X.A.3.d.(5)(j) of the preamble of this proposed rule.

We note that there are audit and record retention requirements under the Medicare Shared Savings Program (42 CFR 425.314) and in current models being tested under section 1115A (such as under 42 CFR 510.110 for the CMS Innovation Center's Comprehensive Care for Joint Replacement Model). Building off those existing requirements, we propose in § .135(a), that the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of a CMS Innovation Center model. Additionally, in order to align with the policy of current models being tested by the CMS Innovation Center, we are proposing that the TEAM participant and its TEAM Collaborators must maintain and give the Federal Government, including, but not limited to, CMS, HHS, and the Comptroller General, or their designees, access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the CMS Innovation Center model, including, without limitation, documents and other evidence regarding all of the following:

- Compliance by the TEAM participant and its TEAM Collaborators with the terms of the CMS Innovation Center model, including proposed new subpart A of proposed part 512.
- The accuracy of model-specific payments made under the CMS Innovation Center model.
- The TEAM participant's payment of amounts owed to CMS, or payment adjustments, under the CMS Innovation Center model.
- Quality measure information and the quality of services performed under the terms of the CMS Innovation Center model, including proposed new subpart A of proposed part 512.

Utilization of items and services furnished under the CMS Innovation Center model.

- The ability of the TEAM participant to bear the risk of potential losses and to repay any losses through claims adjustments to CMS, as applicable.
- Patient safety under TEAM.
- Any other program integrity issues.

We propose that TEAM participants must maintain the documents and other evidence for a period of 6 years from the last payment determination for the TEAM participant under the CMS Innovation Center model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

- CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the TEAM participant at least 30

days before the normal disposition date; or

- There has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

If CMS notifies the TEAM participant of a special need to retain a record or group of records at least 30 days before the normal disposition date, we propose that the records must be maintained for such period of time determined by CMS. We also propose that, if CMS notifies the TEAM participant of a special need to retain records or there has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant or its TEAM Collaborators, the TEAM participant must notify its TEAM Collaborators of the need to retain records for the additional period specified by CMS. This provision will ensure that that the government has access to the records.

To avoid any confusion or disputes regarding the timelines outlined in this section of this proposed rule, we propose to define the term ''days'' to mean calendar days.

We invite public comment on these proposed provisions described at § 512.586 regarding audits and record retention.

Historically, the CMS Innovation Center has required participants in section 1115A models to retain records for at least 10 years, which is consistent with the outer limit of the statute of limitations for the Federal False Claims Act and is consistent with the Shared Savings Program's policy outlined at 42 CFR 425.314(b)(2). For this reason, we also solicit public comments on whether we should require hospital participants and TEAM Collaborators to maintain records for less than 10 years.

k. Data Sharing

(1) Overview

In this proposed rule, we aim to incentivize TEAM participants to engage in care redesign efforts to improve quality of care and reduce Medicare FFS spending for beneficiaries included in the model during the anchor hospitalization or anchor procedure and the 30 days post-discharge from the hospital or hospital outpatient department. These care redesign efforts would require TEAM participants to work with and coordinate care with other health care providers and suppliers to improve the quality and efficiency of care for Medicare beneficiaries.

We have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the BPCI Advanced and CJR models, both of which make certain Medicare data available to participants to better enable them to achieve their goals. For example, both the BPCI Advanced and CJR participants may request to receive beneficiary-identifiable claims data and financial performance data from the baseline period and throughout their tenure in the model to help them better understand the FFS beneficiaries that are receiving services from their providers and help them improve quality of care and conduct care coordination and other care redesign activities to improve patient outcomes or reduce health care for beneficiaries that could have initiated an episode in the model.

Based on our experience with these efforts, as set forth later in this section, we propose to make certain beneficiary-identifiable claims data and regional aggregate data available to participants in TEAM regarding Medicare FFS beneficiaries who may initiate an episode and be attributed to them in the model. However, we also expect that TEAM participants are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

(2) Beneficiary-Identifiable Claims Data

(a) Legal Authority To Share Beneficiary-Identifiable Data

We believe that TEAM participants may need access to certain Medicare beneficiary-identifiable data for the purposes of evaluating their performance, conducting quality assessment and improvement activities, conducting population-based activities relating to improving health or reducing health care costs, or conducting other health care operations listed in the first or second paragraph of the definition of ''health care operations'' under the HIPAA Privacy Rule, 45 CFR 164.501. We recognize that there are issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and that several laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits the disclosure. Here, the HIPAA Privacy Rule would allow for the proposed disclosure of individually identifiable health information by CMS. In this proposed rule, we propose to make TEAM participants accountable for quality and cost outcomes for TEAM beneficiaries during an anchor hospitalization or anchor procedure and during the 30-day post-discharge period. We believe that it is necessary for the purposes of this model to offer TEAM participants the ability to request summary or raw beneficiary-identifiable claims data for a 3-year baseline period as well as on a monthly basis during the performance year to help TEAM participants engage in care coordination and quality improvement activities for TEAM beneficiaries in an episode. For the 3-year baseline period, TEAM participants would only receive beneficiary-identifiable claims data for beneficiaries that initiated an episode in their hospital or hospital outpatient department in the 3-year baseline period, and the beneficiary-identifiable claims data shared with the TEAM participant would be limited to the items and services included in the episode. In other words, the TEAM participant would not receive beneficiary-identifiable claims data for beneficiaries that were admitted to their hospital or hospital outpatient department and did not initiate an episode in the baseline period. Nor would the TEAM participant receive beneficiary-identifiable claims data, for beneficiaries who did initiate an episode in their hospital or hospital outpatient department during the baseline period, for items and services that are not included in an episode, such as a primary care visit 5 days before the episode or a hospital readmission 1 day after the episode ends. We are proposing to apply a similar approach for the beneficiary-identifiable claims data sharing during the performance year. We believe that these data would constitute the minimum information necessary to enable the TEAM participant to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the TEAM participant and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually

identifiable health information that is ''protected health information'' or PHI in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule, without the individual's authorization. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. Hospitals, which would be TEAM participants, and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. Since TEAM participants are hospitals who are covered entities and are the only entity able to request the beneficiary-identifiable data and with whom CMS would share the beneficiary-identifiable data, we believe that the proposed disclosure of the beneficiary claims data for an anchor hospitalization or an anchor procedure plus 30-day post-discharge for episodes included under the TEAM model would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501).

Under our proposal, TEAM participants would be using the data on their patients to evaluate the performance of the TEAM participant and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a TEAM participant to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities, specifically hospitals that are TEAM participants that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed, or requested to a ''minimum necessary'' to accomplish the intended purpose of the use, disclosure, or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements, as described in section X.A.3.k.(2).(c). of the preamble of this proposed rule, would constitute the minimum data necessary to accomplish the TEAM's model goals of the TEAM participant.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. For the proposed TEAM, the system of records would be covered in Master Demonstration, Evaluation, and Research Studies (DERS) for the Office of Research, Development and Information (ORDI) system of record (72 FR 19705). We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

We note that, as is the case with the CJR model, in this proposed rule, we propose to disclose beneficiary-identifiable data to only the hospitals that are bearing risk for episodes and not with their collaborators. As stated in the final CJR rule (80 FR 73515), we believe that the hospitals that are specifically held financially responsible for an episode should make the determination as to which data are needed to manage care and care processes with their collaborators as well as which data they might want to re-disclose, if any, to their collaborators provided they are in compliance with the HIPAA Privacy Rule.

We believe our data sharing proposals are permitted by and are consistent with the authorities and protections available under the aforementioned statutes and regulations. We seek comments on our proposals regarding the authority to share beneficiary-identifiable data with TEAM participants.

(b) Summary and Raw Beneficiary-Identifiable Claims Data Reports

Based on our experience with BPCI Advanced and CJR participants, we recognize that TEAM participants could vary with respect to the kinds of beneficiary-identifiable claims information that would best meet their needs. For example, while many TEAM participants might have the ability to analyze raw claims data, other TEAM participants could find it more useful to have a summary of these data. Given this, we propose to make beneficiary-identifiable claims data for episodes in TEAM available through two formats, summary and raw, both for the baseline period and on an ongoing monthly basis during their participation in the model as we do for BPCI Advanced and CJR. Summary beneficiary-identifiable claims data summarizes the claims data by combining and categorizing claims data to provide a broad view of the TEAM participant's health care expenditures and utilization. For example, a TEAM participant may use summary beneficiary-identifiable data to identify total episode spending for a given episode category across all of a TEAM participant's episodes in a given performance year. Raw beneficiary-identifiable claims data is unrefined and has not been grouped or combined and includes the specific claims fields, as described in the minimum necessary data section X.A.3.k.(2).(c). of the

preamble of this proposed rule, at the episode level. For example, a TEAM participant may use raw beneficiary-identifiable data to look at a particular episode to identify the diagnosis code(s) that were associated with a hospital readmission for a TEAM beneficiary.

First, for TEAM participants who wish to receive summary Medicare Parts A and B claims data, we propose to offer TEAM participants, that enter into a TEAM data sharing agreement with CMS, as specified in section X.A.3.k.(6). of the preamble of this proposed rule, the option to submit a formal data request for summary beneficiary-identifiable claims data that have been aggregated to provide summary-level spending and utilization data on TEAM beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. Such summary beneficiary-identifiable claims data would provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular TEAM participant reflects that, relative to their peers, a certain provider is associated with significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs, that may be evidence that the TEAM participant could consider, among other things, the appropriateness of that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Secondly, for TEAM participants who wish to receive raw Medicare Parts A and B claims data, we propose to offer TEAM participants, that enter into a TEAM data sharing agreement with CMS, the opportunity to submit a formal data request for raw beneficiary-identifiable claims data for TEAM beneficiaries who would be in an episode during the baseline period and performance years in accordance with applicable privacy and security laws and established privacy and security protections. These raw beneficiary-identifiable claims data would be much more detailed compared to the summary beneficiary-identifiable claims data and include all beneficiary-identifiable claims for all episodes in TEAM. In addition, they would include episode summaries, indicators for excluded episodes, diagnosis and procedure codes, and enrollment and dual eligibility information for beneficiaries that initiate episodes in TEAM. Through analysis, these raw beneficiary-identifiable claims data would provide TEAM participants with information to improve their ability to coordinate and target care strategies as well as to monitor, understand, and manage utilization and expenditure patterns. Such data would also aid them in developing, targeting, and implementing quality improvement programs and initiatives.

The summary and raw beneficiary-identifiable data would allow TEAM participants to assess summary and raw data on their relevant TEAM beneficiary population, giving them the flexibility to utilize the data based on their analytic capacity. Therefore, for both the baseline period and at a minimum on a monthly basis during an TEAM participant's performance year, we propose to provide TEAM participants with an opportunity to request summary beneficiary-identifiable claims data and raw beneficiary-identifiable claims data that would meet minimum necessary requirements in 45 CFR 164.502(b) and 164.514(d) and include Medicare Parts A and B beneficiary-identifiable claims data for TEAM beneficiaries in an episode during the 3-year baseline period and performance year. This means the summary and raw beneficiary-identifiable claims data would encompass the total expenditures and claims for the proposed episodes, including the anchor hospitalization or anchor procedure, and all non-excluded items and services in an episode covered under Medicare Parts A and B within the 30 days after discharge, including hospital care, post- acute care, and physician services for the TEAM participant's beneficiaries.

We propose that if a TEAM participant wishes to receive beneficiary-identifiable claims data, they must submit a formal request for data on an annual basis in a manner form and by a date specified by CMS, indicating if they want summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and sign a TEAM data sharing agreement. To comply with applicable laws and safeguards, we propose the TEAM participant must attest that—

- The TEAM participant is requesting claims data of TEAM beneficiaries who would be in an episode during the baseline period or performance year as a HIPAA-covered entity;
- The TEAM participant's request reflects the minimum data necessary for the TEAM participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501;
- The TEAM participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all TEAM beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

We propose that the summary and raw beneficiary-identifiable data would be packaged and sent to a data portal (to which the TEAM participants must request and be granted access) in a ''flat'' or binary format for the TEAM participant to retrieve. We also note that, for both the summary and raw beneficiary-identifiable claims data, we would exclude information that is subject to the regulations governing the confidentiality of substance use disorder patient records (42 CFR part 2) from the data shared with a TEAM participant. We believe our proposal to make data available to TEAM participants, through the most appropriate means, may be useful to TEAM participants to determine appropriate ways to increase the coordination of care, improve quality, enhance efficiencies in the delivery system, and otherwise achieve the goals of the proposed model. TEAM beneficiaries would be informed of TEAM and the potential sharing of Medicare beneficiary-identifiable claims data through the beneficiary notification, as discussed in section X.A.3.i.(2) of the preamble of this proposed rule. Further, CMS would make beneficiary-identifiable claims data available to a TEAM participant for beneficiaries who may be included in episodes, in accordance with applicable privacy and security laws and only in response to the TEAM participant's request for such data, through the use of an executed TEAM data sharing agreement with CMS.

We request comments on this proposal to share beneficiary-identifiable claims data with TEAM participants at § 512.562(b).

(c) Minimum Necessary Data

We propose TEAM participants must limit their beneficiary-identifiable data requests, for TEAM beneficiaries who are in an episode during the baseline period or performance year, to the minimum necessary to accomplish a permitted use of the data. We propose

the minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

- Medicare beneficiary identifier (ID).
- Procedure code.
- Gender.
- Diagnosis code.
- Claim ID.
- The from and through dates of service.
- The provider or supplier ID.
- The claim payment type.
- Date of birth and death, if applicable.
- Tax identification number.
- National provider identifier.

We seek comment on the minimum data necessary beneficiary-identifiable information for TEAM participants to request beneficiary-identifiable information for purposes of conducting permissible health care operations purposes under this model at § 512.562(c).

(3) Regional Aggregate Data

As discussed in section X.A.3.d.(3) of the preamble of this proposed rule, we propose to incorporate regional pricing data when establishing target prices for TEAM participants, similar to the CJR model's target prices that are constructed at the regional level. As indicated in the CJR final rule (80 FR 73510), we finalized our proposal to share regional pricing data with CJR participants because it was a factor affecting target prices. Given some of the similar features between the CJR model and the TEAM proposed in this proposed rule, particularly our proposal to incorporate regional pricing data when establishing target prices under the model, we propose to provide regional aggregate expenditure data available for all Parts A and B claims associated with episodes in TEAM for the U.S. Census Division in which the TEAM participant is located, as we similarly provide to hospitals participating in the CJR model. Specifically, we propose to provide TEAM participants with regional aggregate data on the total expenditures during an anchor hospitalization or anchor procedure and the 30-day post-discharge period for all Medicare FFS beneficiaries who would have initiated an episode under our proposed episode definitions in section X.A.3.b. of the preamble of this proposed rule during the baseline period and performance years. This data would be provided at the regional level; that is, we propose to share regional aggregate data with a TEAM participant for episodes initiated in the U.S. Census Division where the TEAM participant is located. These regional aggregate data would be in a format similar to the proposed summary beneficiary-identifiable claims data and would provide summary information on the average episode spending for episodes in TEAM in the U.S. Census Division in which the TEAM participant is located. However, the regional aggregate data would not be beneficiary-identifiable and would be de-identified in accordance with HIPAA Privacy Rule, 45 CFR 164.514(b). Further, the regional aggregate data would also comply with CMS data sharing requirements, including the CMS cell suppression policy which stipulates that no cell (for example, admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. Given the regional aggregate data is de-identified, we propose TEAM participants would not have to submit a request to receive this data and the data would not be subject to the terms and conditions of the TEAM data sharing agreement.

We seek comments on our proposal at § 512.562(d) to provide these data to TEAM participants.

(4) Timing and Period of Baseline Period Data

We recognize that providing the ability for TEAM participants to request the summary and raw beneficiary-identifiable claims baseline data and receive regional aggregate baseline data would be important for TEAM participants to be able to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation, and that early provision of this data, specifically before the model start date, as defined in § 512.505, could facilitate their efforts to do so. Also, as discussed in section X.A.3.d.(3)(a) of the preamble of this proposed rule, target prices would be calculated using a TEAM participant's historical episode spending during their baseline period. Further, we believe that TEAM participants would view the episode payment model effort as one involving continuous improvement. As a result, changes initially contemplated by a TEAM participant could be subsequently revised based on updated information and experiences.

Therefore, as with the BPCI Advanced model, we propose to make 3-years of baseline period data available to TEAM participants, who enter into a TEAM data sharing agreement with CMS, for beneficiaries who would have been included in an episode had the model been implemented during the baseline period, and intend to make these data available upon request prior to the start of each performance year and in accordance with applicable privacy and security laws and established privacy and security protections. We would provide the 3 years of baseline period data for the summary and raw beneficiary-identifiable data and for the regional aggregate data. We believe that 3 years of baseline period data is sufficient to support a TEAM participant's ability to detect unnecessary episode spending, coordinate care, and identify areas for practice transformation. We believe that if a TEAM participant has access to baseline period data for the 3-year period for each performance year used to set target prices, then it would be better able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality. We considered proposing to make available 4 years of baseline period data, or offering 1 year of baseline period data, but we believe offering 4 years of baseline period data would not be necessary since target prices in TEAM are constructed from a 3-year baseline period and 1 year of data may not sufficiently help TEAM participants identify areas to improve beneficiary health and care coordination or reducing health costs.

Therefore, we propose that the 3-year period utilized for the baseline period match the baseline data used to create TEAM participants target prices every performance year, and roll forward one year every performance year, as discussed in section X.A.3.d.(3)(a) of the preamble of this proposed rule. Specifically, we propose that the baseline period data for the summary and raw beneficiary-identifiable data reports and regional aggregate data report would be shared annually at least 1 month prior to the start of a performance year and available for episodes for each of the following performance years:

- Performance Year 1: Episodes that began January 1, 2022 through December 31, 2024
- Performance Year 2: Episodes that began January 1, 2023 through December 31, 2025
- Performance Year 3: Episodes that began January 1, 2024 through December 31, 2026
- Performance Year 4: Episodes that began January 1, 2025 through December 31, 2026
- Performance Year 5: Episodes that began January 1, 2026 through December 31, 2027

We request comments on these proposals at proposed § 512.562(b)(6)(i) and § 512.562(d)(1)(i) to share beneficiary-identifiable data and regional aggregate data for a 3-year

baseline period at least 1 month prior to the start of a performance year.

(5) Timing and Period of Performance Year Data

The availability of periodically updated raw and summary beneficiary-identifiable claims data and regional aggregate data would assist TEAM participants to identify areas where they might wish to change their care practice patterns, as well as monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated raw and summary beneficiary-identifiable claims data and regional aggregate data available to TEAM participants, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions, described in 45 CFR 164.502(b) and 164.514(d). We believe that monthly data updates would align with a 30-day post-discharge episode window given the episode's duration and the need to share data in a timely manner and identify areas for care improvement. Accordingly, we are proposing to make updated raw and summary beneficiary-identifiable claims data and regional aggregate data available for a given performance year to TEAM participants upon receipt of a request for such information and execution of a TEAM data sharing agreement with CMS, that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met, as frequently as on a monthly basis during the performance year and continue sharing the claims data for up to 6 months beyond the end of that performance year to capture claims run out. We believe 6 months of claims run out is sufficient given that an internal review of Medicare claims data found that the majority of Medicare claims had been received, and were considered final, by 6 months after the date of service and is also consistent with how we are proposing claims run out for the reconciliation process, as described in section X.A.3.d.(5). of the preamble of this proposed rule.[706]

To accomplish this for the first performance year of the TEAM (2026), we would propose to provide, upon request and execution of a TEAM data sharing agreement with CMS, and in accordance with the HIPAA Privacy Rule, beneficiary-identifiable claims data and aggregate regional data from January 1, 2026 to December 30, 2026 on as frequently as a running monthly basis, as claims are available. We would continue sharing beneficiary-identifiable claims data and regional aggregate data for episodes in performance year 1 for an additional 6 months, so until June 30, 2027, to capture claims run out for items and services billed during this time period. These datasets would represent all potential episodes that were initiated in 2026 and capture sufficient amount of time, up to 6 months, for relevant claims to have been processed. We would limit the content of this data set to the minimum data necessary for the TEAM participant to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This data sharing process would continue each performance year of TEAM. We considered proposing to extend this period to capture more than 30 days of data or updating on a quarterly frequency. However, we do not believe this would benefit the TEAM participant since it may create challenges to timely identify potential TEAM beneficiaries for care coordination efforts. We seek comment on whether we should consider extending the period to capture more than 30 days of data or updating the data on a frequency other than monthly.

We seek comments on this proposal at proposed § 512.562(b)(6)(ii) and § 512.562(d)( )(ii) to make beneficiary-identifiable data and regional aggregate data available on a monthly basis and for up to 6 months after a performance year.

(6) TEAM Data Sharing Agreement

We propose that if a TEAM participant wishes to retrieve the beneficiary-identifiable data, the TEAM participant would be required to first complete, sign, and submit—and thereby agree to the terms of—a data sharing agreement with CMS, which we would call the TEAM data sharing agreement. We propose to define the TEAM data sharing agreement as an agreement between the TEAM participant and CMS that includes the terms and conditions for any beneficiary-identifiable data being shared with the TEAM participant under § 512.562. Further, we propose to require TEAM participants to comply with all applicable laws and the terms of the TEAM data sharing agreement as a condition of retrieving the beneficiary-identifiable data. We also propose that the TEAM data sharing agreement would include certain protections and limitations on the TEAM participant's use and further disclosure of the beneficiary-identifiable data and would be provided in a form and manner specified by CMS. Additionally, we propose that a TEAM Participant that wishes to retrieve the beneficiary-identifiable data would be required to complete, sign, and submit a signed TEAM data sharing agreement at least annually. We believe that it is important for the TEAM Participant to complete and submit a signed TEAM data sharing agreement at least annually so that CMS has up-to-date information that the TEAM participant wishes to retrieve the beneficiary-identifiable data and information on the designated data custodian(s). As described in greater detail later in this section, we propose that a designated data custodian would be the individual(s) that a TEAM participant would identify as responsible for ensuring compliance with all privacy and security requirements and for notifying CMS of any incidents relating to unauthorized disclosures of beneficiary-identifiable data.

CMS believes it is important for the TEAM participant to first complete and submit a signed TEAM data sharing agreement before it retrieves any beneficiary-identifiable data to help protect the privacy and security of any beneficiary-identifiable data shared by CMS with the TEAM participant. There are important sensitivities surrounding the sharing of this type of individually identifiable health information, and CMS must ensure to the best of its ability that any beneficiary-identifiable data that it shares with TEAM participants would be further protected in an appropriate fashion.

We considered an alternative proposal under which TEAM participants would not need to complete and submit a signed TEAM data sharing agreement, but we concluded that, if we proceeded with this option, we would not have adequate assurances that the TEAM participants would appropriately protect the privacy and security of the beneficiary-identifiable data that we are proposing to share with them. We also considered an alternative proposal under which the TEAM participant would need to complete and submit a signed TEAM data sharing agreement only once for the duration of the TEAM. However, we concluded that this similarly would not give CMS adequate assurances that the TEAM participant would protect the privacy and security of the beneficiary-identifiable data from CMS. We concluded that it is critical that we have up-to-date information and designated data custodians, and that requiring the TEAM participant to

[706] Medicare Claims Maturity: CCW White Paper accessed at *https://www2.ccwdata.org/web/guest/white-papers?p_l_back_url=%2Fweb%2Fguest%2Fsearch%3Fq%3Dmedicare%2Bclaims%2Bmaturity* on Jan, 26, 2024.

submit an TEAM data sharing agreement at least annually would represent the best means of achieving this goal.

We solicit public comment on our proposal to define TEAM data sharing agreement at § 512.505. We also seek comment on our proposal to require, in § 512.562(e)(2), that the TEAM participant agree to comply with all applicable laws and the terms of the TEAM data sharing agreement as a condition of retrieving the beneficiary-identifiable data, and on our proposal in § 512.562(e)(1) that the TEAM participant would need to submit the signed TEAM data sharing agreement at least annually if the TEAM participant wishes to retrieve the beneficiary-identifiable data.

(a) Content of TEAM Data Sharing Agreement

We are proposing that, under the TEAM data sharing agreement, TEAM participants would agree to certain terms, namely: (1) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the proposed TEAM; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the TEAM data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the TEAM participant or performs a similar function for the TEAM participant, to the same terms and conditions to which the TEAM participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the TEAM participant under the TEAM; and (4) that if the TEAM participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the TEAM data sharing agreement, the TEAM participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. CMS believes that these terms for sharing beneficiary-identifiable data with TEAM participants are appropriate and important, as CMS must ensure to the best of its ability that any beneficiary identifiable data that it shares with TEAM participants would be further protected by the TEAM participant, and any business associates of the TEAM participant, in an appropriate fashion. CMS believes that these proposals would allow CMS to accomplish that.

CMS seeks public comment on the additional privacy, security, breach notification, and other requirements that we would include in the TEAM data sharing agreement. CMS has these types of agreements in place as part of the governing documents of other models tested under section 1115A of the Act and in the Medicare Shared Savings Program. In these agreements, CMS typically requires the identification of data custodian(s) and imposes certain requirements related to administrative, physical, and technical safeguards relating to data storage and transmission; limitations on further use and disclosure of the data; procedures for responding to data incidents and breaches; and data destruction and retention. These provisions would be imposed in addition to any restrictions required by law, such as those provided in the HIPAA privacy, security and breach notification regulations. These provisions would not prohibit the TEAM participant from making any disclosure of the data otherwise required by law.

CMS also seeks public comment on what disclosures of the beneficiary-identifiable data might be appropriate to permit or prohibit under the TEAM data sharing agreement. For example, CMS is considering prohibiting, in the TEAM data sharing agreement, any further disclosure, not otherwise required by law, of the beneficiary-identifiable data to anyone who is not a HIPAA covered entity or business associate, as defined in 45 CFR 160.103, or to an individual practitioner in a treatment relationship with the TEAM beneficiary, or that practitioner's business associates. Such a prohibition would be similar to that imposed by CMS in other models tested under section 1115A of the Act in which CMS shares beneficiary identifiable data with model participants.

CMS is considering these possibilities because there exist important legal and policy limitations on the sharing of the beneficiary-identifiable data and CMS must carefully consider the ways in which and reasons for which we would provide access to this data for purposes of the TEAM. CMS believes that some TEAM participants may require the assistance of business associates, such as contractors, to perform data analytics or other functions using this beneficiary-identifiable data to support the TEAM participant's review of their care management and coordination, quality improvement activities, or clinical treatment of TEAM beneficiaries. CMS also believes that this beneficiary-identifiable data may be helpful for any HIPAA covered entities who are in a treatment relationship with the TEAM beneficiary.

We seek public comment on how a TEAM participant might need to, and want to, disclose the beneficiary-identifiable data to other individuals and entities to accomplish the goals of the TEAM, in accordance with applicable law.

Under our proposal, the TEAM data sharing agreement would include other provisions, including requirements regarding data security, retention, destruction, and breach notification. For example, we are considering including, in the TEAM data sharing agreement, a requirement that the TEAM participant designate one or more data custodians who would be responsible for ensuring compliance with the privacy, security and breach notification requirements for the data set forth in the TEAM data sharing agreement; various security requirements like those found in other models tested under section 1115A of the Act, but no less restrictive than those provided in the relevant Privacy Act system of records notices; how and when beneficiary-identifiable data could be retained by the TEAM participant or its downstream participants of the beneficiary identifiable data; procedures for notifying CMS of any breach or other incident relating to the unauthorized disclosure of beneficiary-identifiable data; and provisions relating to destruction of the data. These are only examples and are not the only terms CMS would potentially include in the TEAM data sharing agreement.

We solicit public comment on this proposal that CMS, by adding § 512.562(e)(1)(ii), would impose certain requirements in the TEAM data sharing agreement related to privacy, security, data retention, breach notification, and data destruction.

Finally, CMS proposes, at § 512.562(e)(1)(iv), that the TEAM data sharing agreement would include a term providing that if the TEAM participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the TEAM data sharing agreement, the TEAM participant would no longer be eligible to retrieve beneficiary-identifiable data under proposed § 512.562(b) and may be subject to additional sanctions and penalties available under law. We also propose that if CMS determines that one or more grounds for remedial action specified in § 512.592(a) has taken

place, CMS may discontinue the provision of data sharing and reports to the model participant. We propose that CMS may take remedial action if the model participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

We solicit public comment on this proposal, to prohibit the TEAM participant from obtaining beneficiary-identifiable data pertaining to the TEAM if the TEAM participant fails to comply with applicable laws and regulations, the terms of the TEAM, or the TEAM data sharing agreement.

l. Referral to Primary Care Services

As noted elsewhere in this proposed rule, the CMS Innovation Center has placed accountable care at the center of our comprehensive strategy, with a goal of 100 percent of Medicare FFS beneficiaries (and most Medicaid beneficiaries as well) being in an accountable care relationship by 2030. Achieving the goal of increasing the number of beneficiaries in accountable care relationships and testing models and innovations supporting access to high-quality, integrated specialty care across the patient journey—both longitudinally and for procedural or acute services—will greatly depend on numerous factors, including the models and initiatives available for providers in value-based payment, but also our ability to create incentives for providers and suppliers to coordinate care across different aspects of care. With TEAM, we have an opportunity to further integrate care during the transition from an acute event- an episode- back to longitudinal care relationships, such as primary care.

Acute care hospitals commonly refer patients back to primary care providers in the community upon discharge from the hospital, given the connection between ongoing care follow-up and reduced readmissions, among other benefits. While the hospital Conditions of Participation for discharge planning at § 482.43(a) outline requirements for referring patients to post-acute providers as well as community-based providers and suppliers, there is no specific requirement for referral back to a supplier, as defined in in section 1861(d) of the Act and codified at § 400.202, of primary care services, as defined in section 1842(i)(4) of the Act, at hospital discharge for all patients. Under TEAM, we are proposing that TEAM participants be required to include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. We also propose that the TEAM participant must comply with beneficiary freedom of choice requirements, as described in section X.A.3.i.(2) of the preamble of this proposed rule and proposed at § 512.582(a), and not limit a TEAM beneficiary's ability to choose among Medicare providers or suppliers. If a TEAM participant fails to comply with requiring a referral to a supplier of primary care services during hospital discharge planning then we propose the TEAM participant would be subject to remedial action, as described in section X.A.1.f. of the preamble of this proposed rule.

Referring TEAM beneficiaries to a supplier of primary care services would require the TEAM participant to confirm the TEAM beneficiary's primary care provider status during the anchor hospitalization or anchor procedure and make the referral to primary care services by the point of the hospital discharge. By requiring a referral to primary care services, TEAM would be used to connect TEAM beneficiaries with ongoing care beyond the course of the episode. Further, TEAM participants would be required to ensure TEAM beneficiaries preference of suppliers are taken into account to ensure proper beneficiary protections.

We recognize that TEAM is comprised of procedural episodes, which may mean TEAM beneficiaries have a greater need to stay connected to their surgeon or specialist involved in their episode, rather than make a connection to primary care for ongoing care. Additionally, we also recognize requiring a referral to primary care services for all TEAM beneficiaries may increase TEAM participant burden. However, we believe many hospitals already have this perform this process as a standard of care for discharge planning, therefore the burden on TEAM participants should be minimal.

We seek comment on our proposal at proposed § 515.564 to require TEAM participants during hospital discharge planning to make a referral to a supplier of primary care services for a TEAM beneficiary on or prior to discharge from the anchor hospitalization or anchor procedure. We also seek comment on whether there are other mechanisms or ways to connect the TEAM beneficiary back to a supplier of primary care services that would support a patient's continuum of care.

m. Alternative Payment Model Options

(1) Background

As specified in the Quality Payment Program (42 CFR 414.1415), an APM must meet three criteria to be considered an Advanced APM:

- Beginning with the calendar year 2025 Qualifying APM Participant (QP) performance period, an Advanced APM must require all eligible clinicians in each participating APM Entity, or for APMs in which hospitals are the participants, each hospital, to use Certified Electronic Health Record Technology (CEHRT).
- An Advanced APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM.
- Meet the financial risk standard under 42 CFR 414.1415(c)(1) or (2) and the nominal amount standard under 42 CFR 414.1415(c)(3) or (4).

We seek to align the design of TEAM with the Advanced APM criteria in the Quality Payment Program and enable CMS to have the necessary information on eligible clinicians to make the requisite QP determinations. Eligible clinicians, as defined in 42 CFR 414.1305, that are captured on a CMS-maintained list for the APM entity, as defined in 42 CFR 414.1305, may be eligible to receive benefits for participating in an Advanced APM, including burden reduction and financial incentives. We propose that the TEAM participant would be considered the APM entity, but that the TEAM participant's eligible clinicians may be assessed for QP determinations depending on which track the TEAM participant is in and whether the CEHRT criteria are met. However, we also seek to ensure the design of TEAM meets the Merit-based Incentive Payment System (MIPS) APM criteria and that CMS has the necessary information on MIPS eligible clinicians, as defined in 42 CFR 414.1305, so that they may be eligible for certain scoring benefits under MIPS. We therefore propose to adopt two different APM options for TEAM—an AAPM option in which TEAM participants would attest to meeting the CEHRT standards and in which the TEAM participant's eligible clinicians may be assessed for QP determinations (to the extent TEAM is determined to be an Advanced APM for Track 2 and Track 3), and a non-AAPM option in which TEAM participants would not meet CEHRT or financial risk standards and in which the TEAM participant's MIPS eligible clinicians may be assessed for reporting and scoring through the APM Performance

Pathway (APP) (to the extent the TEAM is determined to be a MIPS APM for all tracks).

(2) TEAM APM Options

As previously stated, an Advanced APM must require participants to use CEHRT (42 CFR 414.1415(a)), make payment based on quality measures (42 CFR 414.1415(b)) and meet financial risk standards (42 CFR 414.1415(c)). We propose to have two APM options in TEAM: a non-Advanced APM (non-AAPM) option and an Advanced APM (AAPM) option. The non-AAPM option would be for TEAM participants that do not meet the CEHRT or financial risk standards. These TEAM participants may still be considered APM entities in a MIPS APM. The AAPM option would be for TEAM participants in Tracks 2 and 3 that meet the CEHRT and financial risk standards. These TEAM participants would be considered APM entities in an Advanced APM., TEAM participants in Track 1 would automatically be assigned into the non-AAPM option since Track 1 would have no downside financial risk. The financial risk that we propose in Tracks 2 and 3 would meet the generally applicable nominal amount standard, as defined in 42 CFR 414.1415(c)(3), but there may be TEAM participants in Tracks 2 and 3 who do not meet the CEHRT standard. TEAM participants in Tracks 2 or 3 that do not meet and attest to the CEHRT use requirement would fall into the non-AAPM option of TEAM, but these TEAM participants may still be considered APM entities in a MIPS APM. TEAM participants that participate in Tracks 2 or 3 and meet and attest to the CEHRT use requirement would be in the AAPM option of TEAM.

We propose to require TEAM participants who wish to participate in the AAPM option to attest to meeting the CEHRT use requirement that meets the CEHRT definition in our regulations at section 414.1305 on an annual basis prior to the start of each performance year in a form and manner and by a date specified by CMS. We propose that the TEAM participant would be required to retain and provide CMS access to the attestation upon request. We further propose that meeting and attesting to the CEHRT use criteria would be voluntary, and that CMS would assign TEAM participants who choose not to do so to the non-AAPM option. Lastly, we propose to require TEAM participants who wish to participate in the AAPM option to provide their CMS Electronic Health Record (EHR) Certification IDs on an annual basis prior to the end of each performance year in a form and manner and by a date specified by CMS.

We believe that a TEAM participant's decision to meet and attest to the CEHRT use criteria would not create significant additional administrative burden for the TEAM participant. Moreover, the choice of whether to meet and attest to the CEHRT use criteria would not otherwise affect the TEAM participant's requirements or opportunities under the model. However, a TEAM participant's decision to attest to CEHRT use may affect the ability of its clinicians to qualify as a QP. In other words, if a TEAM participant chose not to attest to CEHRT use, its clinicians would not be assessed for QPs status.

We seek comment on our proposals for the TEAM Advanced APM options and the associated requirements at § 512.522. We also seek comment on our proposed definitions for the AAPM option and non-AAPM option at § 512.505.

(3) Financial Arrangements List and Clinician Engagement List

We propose that each TEAM participant would be required to submit information about the eligible clinicians or MIPS eligible clinicians who enter into financial arrangements with the TEAM participant for purposes of supporting the TEAM participants' cost or quality goals as discussed in section X.A.3.g. of the preamble of this proposed rule. This information would enable CMS to make determinations as to eligible clinicians who could be considered QPs based on the services furnished under TEAM (to the extent the model is determined to be an AAPM) and would be necessary for APP reporting and scoring for MIPS eligible clinicians (to the extent the model is determined to be a MIPS APM), We are proposing that for purposes of TEAM, the eligible clinicians or MIPS eligible clinicians could be: (1) TEAM collaborators, as described in section X.A.3.g.(3). of the preamble of this proposed rule, engaged in sharing arrangements with a TEAM participant; (2) PGP, NPPGP, or TGP members who are collaboration agents engaged in distribution arrangements with a PGP, NPPGP, or TGP that is a TEAM collaborator, as described in section X.A.3.g.(5). of the preamble of this proposed rule; or (3) PGP, NPPGP, or TGP members who are downstream collaboration agents engaged in downstream distribution arrangements with a PGP, NPPGP, or TGP that is also an ACO participant in an ACO that is a TEAM collaborator, as described in section X.A.3.g.(6). of the preamble of this proposed rule. The list of physicians and nonphysician practitioners in these three groups that we are proposing to require TEAM participants to submit to CMS would satisfy the criteria to be considered an Affiliated Practitioner List, as defined in § 414.1305. We are proposing to use the list submitted by TEAM participants to make determinations regarding which physicians and nonphysician practitioners should receive QP determinations or be reported for the APP based on the services they furnish under TEAM.

We propose for the reasons detailed above that each TEAM participant with eligible clinicians or MIPS eligible clinicians must submit to CMS a financial arrangements list in a form and manner and by the date specified by CMS on a quarterly basis during each performance year, or attest that there are no individuals to report on the financial arrangements list. We believe submission of the financial arrangements list on a quarterly basis would align with the Quality Payment Program's QP determination dates, as described in § 414.1425. We are proposing to define the financial arrangements list as the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent. We propose that the TEAM participant would be required to retain and provide CMS access to the financial arrangements list upon request. The proposed list must include the following information:

- For each TEAM collaborator who is a physician, nonphysician practitioner, or therapist during the performance year—

++ The name, tax identification number (TIN), and national provider identifier (NPI) of the TEAM collaborator; and

++ The start date and, if applicable, end date, for the sharing arrangement between the TEAM participant and the TEAM collaborator.

- For each collaboration agent who is a physician, nonphysician practitioner, or therapist during the performance year—

++ The name, TIN, and NPI of the collaboration agent and the name and TIN of the TEAM collaborator with which the collaboration agent has entered into a distribution arrangement; and

++ The start date and, if applicable, end date, for the distribution arrangement between the TEAM collaborator and the collaboration agent.

• For each downstream collaboration agent who is a physician or nonphysician practitioner, or therapist during the performance year—

++ The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent; and

++ The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

• If there are no individuals that meet the reporting criteria above for TEAM collaborators, collaboration agents, or downstream collaboration agents, then the TEAM participant must attest on a quarterly basis in a form and manner and by a date specified by CMS that there are no individuals to report on the financial arrangements list.

While the proposed submission of the financial arrangements list may create some additional administrative burdens for certain TEAM participants, we expect that TEAM Participants could modify their contractual relationships with their TEAM collaborators and, correspondingly, require those TEAM collaborators to include similar requirements in their contracts with collaboration agents and in the contracts of collaboration agents with downstream collaboration agents.

We also recognize there may be physicians and nonphysician practitioners who would not be listed on the financial arrangements list because they have not entered into a financial arrangement as a TEAM collaborator, collaboration agent, or downstream collaboration agent, but who may nevertheless participate in TEAM activities, as defined at proposed § 512.505, and may be eligible for QP determinations or eligible for APP reporting because they are affiliated with and support the APM Entity. We propose that, in order to capture these physicians and nonphysician practitioners who are not listed on the TEAM participant's financial arrangements list for QP determinations or APP reporting, TEAM participants must also submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis every performance year. We propose to use the clinician engagement list for assessing QP determinations and for APP reporting. The submission of the clinician engagement lists may create some additional administrative burdens for TEAM participants, but we expect the effort to be worthwhile since some of these QP determinations may result in eligible clinicians receiving burden reduction benefits and financial incentives, and some MIPS eligible clinicians may receive MIPS APM scoring benefits.

We are proposing to define the clinician engagement list as the list of eligible clinicians or MIPS eligible clinicians that participate in TEAM activities and have a contractual relationship with the TEAM participant, and who are not listed on the financial arrangements list . We propose that the TEAM participant must submit the list to CMS on a quarterly basis during each performance year in a form and manner and by a date specified by CMS or attest that there are no individuals to report on the clinician engagement list. We believe submission of the clinician engagement list on a quarterly basis would align with the Quality Payment Program's QP determination dates, as described in § 414.1425. We propose that the TEAM participant would be required to retain and provide CMS access to the clinician engagement list upon request. We propose that the clinician engagement list must include the following information:

• For each physician, nonphysician practitioner, or therapist who is not listed on the TEAM participant's financial arrangements list during the performance year but who does have a contractual relationship with the TEAM participant and participates in TEAM activities during the performance year—

++ The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist; and

++ The start date and, if applicable, end date, for the contractual relationship between the physician, nonphysician practitioner, or therapist and the TEAM participant.

• We are proposing that if there are no individuals that meet the requirements to be reported on the clinician engagement list, then the TEAM participant must attest on a quarterly basis in a form and manner and by a date specified by CMS that there are no individuals to report on the clinician engagement list.

We seek comments on the proposal to require TEAM participants to submit a financial arrangements list and clinician engagement list on a quarterly basis or attest that there are no individuals to report. We are especially interested in comments about approaches to information submission, including the content of the lists, and periodicity and method of submission to CMS that would minimize the reporting burden on TEAM participants while providing CMS with sufficient information about eligible clinicians to facilitate QP determinations and APP reporting to the extent that TEAM is considered to be an Advanced APM for Track 2 and Track 3 and a MIPS APM for all tracks, respectively.

n. Interoperability

Improved interoperability of software systems and tools used to manage patients supports the goals of value-based care, enabling care coordination and data-driven decision making to improve outcomes and lower healthcare expenditures. Hospitals use electronic health record (EHR) systems to document patient medical history, which may include clinical data relevant to that person's care, including demographics, clinical notes, medications, vital signs, past medical and surgical history, immunizations, laboratory data and radiology reports. The EHR also has the ability to support other care-related and administrative activities directly or indirectly through various interfaces, including clinical decision support, quality improvement, and population-health outcomes reporting. While EHRs also include capabilities to coordinate care by sharing data in a structured system with other health care providers, health information exchanges (HIEs) and health information networks (HINs), as defined in 45 CFR 171.102, have played an increasingly important role in assisting hospitals to connect with other health care providers and ensure that information supporting care coordination is consistently shared.[707] A hospital may be connected to an HIE or HIN, that focuses on exchange within a defined geographic area, or nationally across systems and regions. Evidence suggests that participation with an entity facilitating cross-system exchange may improve patient outcomes, including decreased hospital readmission rates, as well as decreased utilization, such as repeat laboratory or radiology studies.[708] [709]

Despite the growth of HIEs and HINs, important gaps remain for an infrastructure that supports the seamless exchange of clinical data across disparate healthcare organizations and software vendors. Barriers to

[707] *https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/health-information-exchange.*

[708] Chen, M., Guo, S., & Tan, X. (2019). Does health information exchange improve patient outcomes? Empirical evidence from Florida hospitals. Health Affairs, 38(2), 197–204. *https://doi.org/10.1377/hlthaff.2018.05447.*

[709] Menachemi, N., Rahurkar, S., Harle, C. A., & Vest, J. R. (2018). The benefits of health information exchange: an updated systematic review. Journal of the American Medical Informatics Association, 25(9), 1259–1265. *https://doi.org/10.1093/jamia/ocy035.*

interoperability create silos that limit care coordination between hospitals and other health care providers, especially during care transitions such as a patient being discharged from a hospital to a post-acute care facility. Existing HHS and CMS initiatives aim to support health care organizations engaging in interoperable exchange of health information. The Office of the National Coordinator for Health Information Technology (ONC) launched The Trusted Exchange Framework and Common Agreement (TEFCA), which establishes a universal governance, policy, and technical floor for nationwide interoperability; simplifies connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and enables individuals to gather their healthcare information.[710]

CMS acknowledged the importance of TEFCA in the FY 2023 Inpatient Prospective Payment System (IPPS) final rule (87 FR 48780) by adding the Enabling Exchange under TEFCA (87 FR 49329) as a new measure under the Health Information Exchange Objective for the Medicare Promoting Interoperability Program. Participants in the Medicare Promoting Interoperability Program may also earn credit for the Health Information Exchange Objective by reporting on the previously finalized Health Information Exchange (HIE) Bidirectional Exchange measure (86 FR 45465).

In the CY 2023 Physician Fee Schedule final rule (87 FR 70067 through 70071), CMS also added a new optional measure, Enabling Exchange Under TEFCA, to the Health Information Exchange objective for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category beginning with the CY 2023 performance period/2025 MIPS payment year. Currently, for the CY 2024 performance period/2026 MIPS payment year, MIPS eligible clinicians may fulfill the Health Information Exchange objective via three avenues by reporting: (1) the two Support Electronic Referral Loops measures; (2) the Health Information Exchange Bidirectional Exchange measure; or (3) the Enabling Exchange under TEFCA measure (88 FR 79357 through 79362).

TEAM would like to support TEAM participants' interoperability efforts that could lead to best practices across U.S. health care landscape. However, we recognize that given the existing federal interoperability initiatives, we do not want to create duplicate efforts or create unnecessary burden on TEAM participants. We are seeking comment on how CMS can promote interoperability in the proposed TEAM, in particular, to what extent TEAM participants are planning on participating in TEFCA in the next 1–2 years, as well as other means by which interoperability may support care coordination for an episode. Any further proposals related to interoperability included in TEAM would be done in future notice and comment rulemaking.

o. Evaluation Approach

(1) Background

The proposed TEAM is intended to enable CMS to better understand the effects of bundled payments models on a broader range of Medicare providers and capture a greater number of episodes of care than what is currently available under the CJR model and BPCI Advanced. Obtaining information that is representative of a wide and diverse group of providers and episodes of care will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. All CMS Innovation Center models, which would include the proposed TEAM, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS Innovation Center models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. Outlined later in this section are the proposed design and evaluation methods, the data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the proposed TEAM.

(2) Design and Evaluation Methods

Our evaluation methodology for TEAM would be consistent with the standard CMS Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, BPCI Advanced and the CJR model, and other CMS Innovation Center models. Specifically, the evaluation design and methodology for the proposed TEAM would be designed to allow for a comparison of historic patterns of care among the TEAM participants to any changes made in these patterns in response to the TEAM. In addition, the overall design would include a comparison of TEAM participants with hospitals not participating in TEAM to help us discern simultaneous and competing provider and market level forces that could influence our findings.

Our evaluation methodology for this model builds upon the fact that we are proposing CBSAs to be selected for participation in the model based on a stratified random assignment. In this approach, researchers evaluate the effects of the model on outcomes of interest by directly comparing CBSAs that are randomly selected to participate in the model to a comparison group of CBSs that were not randomly selected for the model (but could have been). Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. With these methodologies, we would be able to examine the experience of the TEAM participants over time relative to those in the comparison group controlling for as many of the relevant confounding factors as is possible. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of care delivery transformation.

In our design, we plan to take into account the impact of the TEAM at the geographic unit level, the hospital level, and at the patient level. We are also considering various statistical methods to address factors that could confound or bias our results. For example, we would use statistical techniques to account for clustering of patients within hospitals and markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Accounting for clustering ensures that we do not overstate our effective sample size by failing to account for the fact that performance of hospitals in a given market may not be fully independent of one another. Alternatively, accounting for clustering may improve statistical precision or allow us to better examine how patterns of performance vary across hospitals. Thus, in our analysis, if a

[710] *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to biased estimates and mistaken inferences.

Finally, we plan to use various statistical techniques to examine the effects of the TEAM while also taking into account the effects of other ongoing interventions such as Medicare Shared Savings Program. For example, we are considering additional regression techniques to help identify and evaluate the incremental effects of adding the TEAM in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

(3) Data Collection Methods

We are considering multiple sources of data to evaluate the effects of the TEAM. We expect to base much of our analysis on secondary data sources such as the Medicare FFS claims. The beneficiary claims data would provide information such as expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission. In conjunction with the secondary data sources mentioned previously, we are considering a CMS-administered survey, guided interviews and focus groups of beneficiaries who were in an episode during the performance year. This survey would be administered to TEAM beneficiaries who were in an episode or similar patients selected as part of a control group. The primary focus of this survey would be to obtain information on the TEAM beneficiary's experience in episodes relative to usual care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey so as to not conflict with or compromise this HCAHPS efforts. Likewise, we are considering a survey administered by CMS with providers including, but not limited to, TEAM participants, physicians, and PAC providers participating in the TEAM. These surveys would provide insight on providers' experience under the model and further information on the care redesign strategies undertaken by health care providers.

In addition, we are considering CMS evaluation contractor administered site visits and focus groups with selected TEAM participants, physicians and PAC providers. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among the providers in TEAM. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to capture variations in implementation as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

We are considering primary data collection efforts with providers and beneficiaries within the control group. The systematic data collection from control group providers would allow for parsing out changes in standard of care from the TEAM impact. Additionally, primary data collection with beneficiaries who received care at control group providers will provide critical information about the impact of the model on self-reported health status, experience of care and overall satisfaction.

(4) Key Evaluation Research Questions

Our evaluation would assess the impact of the TEAM on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of patient experience of care, utilization, outcomes, Medicare expenditures, provider costs, quality, and access. Our key evaluation questions would include, but are not limited to, the following:

- Payment. Is there a reduction in Medicare expenditures in absolute terms? By subcategories? Do the TEAM participants reduce or eliminate variations in expenditures that are not attributable to differences in health status? If so, how have they accomplished these changes? Did TEAM result in net savings to the Medicare program, after accounting for the financial incentives distributed under the model?
- Utilization. Are their changes in Medicare utilization patterns overall and for specific types of services? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes and general clinical judgment of appropriate care?
- Referral Patterns and Market Impact. How has provider behavior in the selected CBSAs changed under the model? Is there evidence of broader changes to the market? Are provider relationships changing over the course of the model? Is the model facilitating continuity of care by connecting beneficiaries with new or existing primary care providers?
- Outcomes/Quality. Is there either a negative or positive impact on quality of care and/or better patient experiences of care? Did the incidence of relevant clinical outcomes such as complications remain constant or decrease? Were there changes in beneficiary outcomes under the model compared to appropriate comparison groups?
- Equity. Were there notable impacts by subgroups based on beneficiary characteristics such as race/ethnicity, dual status, rurality, or other measures of socio-economic disadvantage? How did TEAM participants address health disparities in care? Did the financial performance differ for hospitals furnishing a substantial share of services to uninsured and low-income patients?
- Transformation. Is there evidence that the participants' changes in care delivery, that were made in the response to the model, will be sustained? Did TEAM enable positive spillover effects to other episodes of care, or other providers across the local market of the health system?
- Unintended Consequences. Did TEAM result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the agreed upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? Is so, how, to what extent, and for which beneficiaries or providers?
- Potential for Extrapolation of Results. What was the typical patient case mix in the participating practices and how did this compare to regional and national patient populations? What were the characteristics of participating practices and to what extent were they representative of practices treating Medicare FFS beneficiaries? Was the model more successful in certain types of markets? To what extent would the results be able to be extrapolated to similar markets and/or nationally?
- Explanations for Variations in Impact. What factors are associated with the pattern of results (previously)? Specifically, are they related to:
- Characteristics of the model including variations by year and factors such as presence of downside risk or track assignment?

The TEAM participant's specific features and structure, including such

factors as the number of relevant cases, provider mix, and health system affiliation?

- The TEAM participant's organizational culture and readiness
- The TEAM participant's care redesign interventions and their ability to carry out their proposed intervention?
- Characteristics and nature of interaction with partner providers including PAC provider community?
- Characteristics of market and CBSA such as resources, care infrastructure and supply of physicians and associated providers?
- Characteristics associated with the patient populations served?

(5) Evaluation Period and Anticipated Reports

As discussed in section X.A.3.a.(1). of the preamble of this proposed rule, TEAM would have a 5-year model performance period. The evaluation period would encompass this entire 5-year model performance period and up to 2 years after. We plan to evaluate the TEAM on an annual basis. However, we recognize, that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while CMS intends to conduct periodic summaries to offer useful insight during the course of the model test, a final analysis after the end of the 5-year model performance period will be important for ultimately synthesizing and validating results.

We seek comments on our design, evaluation, data collection methods, and research questions.

p. Decarbonization and Resilience Initiative

In this section, we discuss a proposal for a voluntary Decarbonization and Resilience Initiative within TEAM to assist hospitals in addressing the threats to the nation's health and its health care system presented by climate change and the effects of hospital carbon emissions on health outcomes, health care costs and quality of care. The voluntary initiative would have two elements: technical assistance for all interested TEAM participants and a proposed voluntary reporting option to capture information related Scope 1 and Scope 2 emissions as defined by the Greenhouse Gas Protocol (GHGP) framework,[711] with the potential to add Scope 3 in future years.

The threats presented by climate change to the health of beneficiaries and to health care operations are growing. These include acute climate-related events (for example, wildfires, high—powered storms, flooding) that can harm exposed populations and disrupt service delivery, exacerbations of chronic illness (for example, extreme heat impacts on cardiovascular and pulmonary health) and increases in water-borne and insect-borne illness.[712] These risks often fall disproportionately on traditionally underserved populations, heightening existing health disparities.[713] In view of these challenges, health care organizations must increase their resilience, and understand and address their patients' climate-related health risks.

Health systems have reduced their own significant emissions and ground-level air pollution, often through the introduction of energy efficiency solutions, renewable energy initiatives, and focused efficiency measures in clinical care delivery in areas including surgery (described throughout section X.A.3.p. of the preamble of this proposed rule). We believe these types of cumulative reductions have the potential to make significant contributions to nationwide emission reductions and produce savings. At an individual facility level, these reductions have the potential to save the facility money and enhance their operational resilience (as many sustainable energy solutions can create more energy independence for facilities), meaning decarbonization has bearing on quality of care and cost. More efficient utilization of resources in the surgical setting, specifically, can also reduce cost and improve sustainability; for example, although operating rooms represent a relatively small proportion of hospitals' physical footprint, they typically consume 3–6 times more energy per square foot as the hospital as a whole,[714] account for 40–60 percent of the hospital's supply costs, and produce 30 percent of the hospital's waste.[715]

Because hospital activities (such as surgical procedures) impact emissions and the work of hospitals requires uninterrupted service delivery, we believe TEAM presents an opportunity for CMS to learn more about key strategies for decarbonization (for example, clinical decarbonization approaches, approaches to reducing low-value services and physical waste) and improving resiliency in the health care system. It is hoped that this initiative would help bring savings to the health system and the Medicare Program, consistent with TEAM's goals.

(1) Background

(a) Climate Impact on Health

Climate change driven by greenhouse gas (GHG) emissions threatens patients' health. The health care industry's contribution to those emissions is well-documented and accounts for between 4.4 and 4.6 percent of worldwide GHG emissions.[716] In the U.S. in 2018, GHG emissions from the health care sector accounted for 8.5 percent of total U.S. GHG emissions.[717] According to the National Climate Assessment, the US Government's official report on climate change impacts, children, older adults, and low-income communities are disproportionately affected by climate change and pollution, meaning the Medicare, Medicaid, and CHIP programs bear much of the medical expenses and caregiving services related to emissions.[718] Medicare beneficiaries face several health conditions related to GHG emissions, including, but not limited to, heart disease, stroke, cancer, and

[711] Janet Ranganathan, Laurent Corbier, Pankaj Bhatia, Simon Schultz, Peter Gage, & Kjeli Oren. The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard (Revised Edition). World Business Council for Sustainable Development and World Resources Institute. 2004. *https://ghgprotocol.org/sites/default/files/standards/ghg-protocol-revised.pdf.*

[712] Allison R. Crimmins & Alexa K. Jay (eds.). U.S. Global Change Research Program. Fifth National Climate Assessment. U.S. Global Change Research Program. 2023. *https://nca2023.globalchange.gov/.*

[713] EPA's Office of Atmospheric Programs. Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency. U.S. Environmental Protection Agency. EPA 430–R–21–003. September 2021. *https://www.epa.gov/system/files/documents/2021-09/climate-vulnerability_september-2021_508.pdf.*

[714] Andrea J. MacNeill, Robert Lillywhite, & Carl J. Brown. The Impact of Surgery on Global Climate: A Carbon Footprinting Study Of Operating Theatres in Three Health Systems. Lancet Planetary Health, vol. 1, no. 9, pp. E381–E388. December 2017. *https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(17)30162-6/fulltext.*

[715] Maya A Babu, Angela K Dalenberg, Glen Goodsell, Amanda B Holloway, Marcia M Belau, & Michael J Link. Greening the Operating Room: Results of a Scalable Initiative to Reduce Waste and Recover Supply Costs. Neurosurgery, vol. 85, no. 3, pp. 432–437. September 1, 2019. *https://pubmed.ncbi.nlm.nih.gov/30060055/.*

[716] Matthew J. Eckelman, Kaixin Huang, Robert Lagasse, Emily Senay, Robert Dubrow, & Jodi D. Sherman. Health Care Pollution and Public Health Damage in The United States: An Update. Health Affairs, vol. 39, no. 12, pp. 2071–2079. December 2020. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01247.*

[717] Matthew J. Eckelman, Kaixin Huang, Robert Lagasse, Emily Senay, Robert Dubrow, & Jodi D. Sherman. Health Care Pollution and Public Health Damage in The United States: An Update. Health Affairs, vol. 39, no. 12, pp. 2071–2079. December 2020. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01247.*

[718] USGCRP, 2018: Impacts, Risks, and Adaptation in the United States: Fourth National Climate Assessment, Volume II [Reidmiller, D.R., C.W. Avery, D.R. Easterling, K.E. Kunkel, K.L.M. Lewis, T.K. Maycock, and B.C. Stewart (eds.)]. U.S. Global Change Research Program, Washington, DC, USA, 1515 pp. doi: 10.7930/NCA4.2018.

respiratory diseases.'' [719] More discussion on the impact of climate to Medicare, Medicaid, and CHIP beneficiaries is presented in section X.A.3.p.(1).(c).(v). of the preamble of this proposed rule. The estimated disease burden from U.S. health care pollution is the same order of magnitude as years of life lost as a result of deaths from preventable medical errors.[720]

In keeping with an increased focus on climate resilience and sustainability across HHS, the Biden Administration in 2021 called for the creation of a new Office of Climate Change and Health Equity (OCCHE) within HHS via executive order (E.O. 14008), and for the first time HHS set an aim for addressing climate-related threats to health in its 2022–2026 strategic plan, requiring all Operating Divisions to contribute. In 2022, the Biden Administration launched the Health Sector Climate Pledge, a voluntary commitment to climate resilience and emissions reduction that invites health sector organizations to align with administration goals, cutting GHG emissions by 50 percent by 2030 and achieving net zero emissions by 2050. A group of 133 organizations representing 900 hospitals have signed the Pledge as of November 16, 2023.[721] To support health sector efforts with climate resilience and emissions reduction, OCCHE developed a resource hub [722], featuring tools from across HHS such as a compendium of federal resources for the healthcare sector, information on how to leverage the IRA, an educational webinar series, and the Agency for Healthcare Research and Quality (AHRQ)'s Decarbonization Primer [723] (referred to hereafter as the AHRQ primer). OCCHE also convenes federal health systems (for example, Indian Health Service, Veteran's Health Administration) to collaborate on meeting the administration's goals for emissions reduction, which can inform this initiative.

(b) Greenhouse Gas Protocol and Health

CMS has twice sought and received feedback on approaches to decarbonization and resilience through requests for information in proposed rules. The feedback to these requests was summarized in the final rules. The first request for information was published in the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 proposed rule (87 FR 693 through 694) and a summary presented in the final rule (87 FR 27354). The second was in the in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28478 through 28479) and the summary was presented in the final rule (87 FR 49167). Overall, respondents showed a notable interest in reducing health sector emissions and increasing transparent GHG emissions reporting. CMS continues to update policies to promote energy efficiency and reduce GHG emissions. For example, in 2023, CMS issued the Categorical Waiver Health Care Microgrid System. CMS requires specified providers to have ''emergency power for an essential electrical system (EES) to be supplied by a generator or batter system.'' [724] The waiver permits normal and emergency power to be supplied by sources other than a generator or battery system, including a health care microgrid systems that use sustainable sources of energy such as solar power.

When discussing GHG for this initiative, we refer to the Greenhouse Gas Protocol (GHGP) framework, which is a globally recognized standard for quantifying and reporting on emissions. The framework defines 3 scope levels.[725] We have included examples that relate to health care. [726] [727]

- Scope 1: Direct emissions. Direct GHG emissions occur from sources that are owned or controlled by an organization or company. For health care, Scope 1 captures health care operations such as direct facilities emissions, anesthetic gases, and GHG emissions from leased or owned vehicles.
- Scope 2: Indirect emissions from purchased energy. GHG emissions from the generation of purchased electricity consumed by the organization or company. For health care facilities, Scope 2 includes purchased or acquired electricity, and steam, heat, or cooling consumed by the reporting organization or company.
- Scope 3: Other indirect GHG emissions. Scope 3 allows for the treatment of all other indirect emissions. Scope 3 incorporates upstream and downstream emissions in the supply chain. For health care, Scope 3 may include purchased pharmaceuticals and chemicals, medical devices and supplies, food, water, waste, employee and patient transportation, and additional emissions outside of Scopes 1 and 2. In Scope 3, all purchased and sold goods have an estimated emissions factor for their production, transportation, and life cycle. For example, in a health care setting, Scope 3 emissions may include prescribed medicine such as metered dose inhalers (MDI). Scope 3 uniquely incorporates intangible emissions through the organization's reported investments.

In a 2018 analysis, Scope 1 accounted for 7 percent of the U.S. National Health Care GHG emissions, Scope 2 accounted for 11 percent, and Scope 3 accounted for the remaining 82 percent.[728] We

[719] Joel D. Kaufman, Sara D. Adar, R. Graham Barr, et al. Association Between Air Pollution and Coronary Artery Calcification Within Six Metropolitan Areas in the USA (The Multi-Ethnic Study of Atherosclerosis and Air Pollution): A Longitudinal Cohort Study. Lancet, vol. 388, no. 10045, pp. 696–704. August 13, 2017. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5019949/.*

[720] Joel D. Kaufman, Sara D. Adar, R. Graham Barr, et al. Association Between Air Pollution and Coronary Artery Calcification Within Six Metropolitan Areas in the USA (The Multi-Ethnic Study of Atherosclerosis and Air Pollution): A Longitudinal Cohort Study. Lancet, vol. 388, no. 10045, pp. 696–704. August 13, 2017. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5019949/.*

[721] HHS Office of Climate Change & Health Equity. Health Sector Commitments to Emissions Reduction and Resilience. HHS Office of the Assistant Secretary for Health—Health Sector Pledge. January 3, 2024. *https://www.hhs.gov/climate-change-health-equity-environmental-justice/climate-change-health-equity/actions/health-sector-pledge/index.html.*

[722] HHS Office of Climate Change & Health Equity. Compendium of Federal Resources for Health Sector Emissions Reduction and Resilience. HHS Office of the Assistant Secretary for Health—Health Sector Pledge. December 7, 2023. *https://www.hhs.gov/climate-change-health-equity-environmental-justice/climate-change-health-equity/actions/health-care-sector-pledge/federal-resources/index.html.*

[723] Bhargavi Sampath, Matthew Jensen, Jennifer Lenoci-Edwards, Kevin Little, Hardeep Singh, & Jodi D. Sherman. Reducing Health care Carbon Emissions: A Primer on Measures and Actions for Health Care Organizations to Mitigate Climate Change. U.S. Agency for Healthcare Research & Quality. AHRQ pub. No. 22–M011. September 2023. Reducing Healthcare Carbon Emissions: A Primer on Measures and Actions to Mitigate Climate Change (*ahrq.gov*).

[724] CMS Quality, Safety, & Oversight Group (QSOG) Director and CMS Survey & Operations Group (SOG) Director. Categorical Waiver—Health Care Microgrid Systems (HCMSs). CMS Center for Clinical Standards and Quality reference no. QSO–23–11–LSC. March 31, 2023. *https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/categorical-waiver-health-care-microgrid-systems-hcmss.*

[725] Janet Ranganathan, Laurent Corbier, Pankaj Bhatia, Simon Schultz, Peter Gage, & Kjeli Oren. The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard (Revised Edition). World Business Council for Sustainable Development and World Resources Institute. 2004. *https://ghgprotocol.org/sites/default/files/standards/ghg-protocol-revised.pdf.*

[726] Nick Watts (ed.). Delivering a 'Net Zero' National Health Service. NHS England & NHS Improvement publication no. PAR133. July 2022. B1728-delivering-a-net-zero-nhs-july-2022.pdf (*england.nhs.uk*).

[727] Matthew J. Eckelman, Kaixin Huang, Robert Lagasse, Emily Senay, Robert Dubrow, & Jodi D. Sherman. Health Care Pollution and Public Health Damage in The United States: An Update. Health Affairs, vol. 39, no. 12, pp. 2071–2079. December 2020. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01247.*

[728] Matthew J. Eckelman, Kaixin Huang, Robert Lagasse, Emily Senay, Robert Dubrow, & Jodi D. Sherman. Health Care Pollution and Public Health

believe that Scopes 1 and 2 emissions reduction measures represent areas where there are significant opportunities to increase hospital operating efficiency and reduce operating costs. Therefore, we are proposing in section X.A.3.p.(4). of the preamble of this proposed rule that TEAM participants could voluntarily report on organizational questions and Scopes 1 and 2 metrics, as participants in TEAM would have direct oversight of these items. While we are not proposing Scope 3 metrics in this rule, we recognize Scope 3 accounts for the largest portion of GHG emissions. Therefore, we are seeking comment in section X.A.3.p.(4).(a).(vii). of the preamble of this proposed rule on how we might be able to standardize and collect this information in the future.

(c) Rationale for Establishing the Decarbonization and Resilience Initiative

(i) GHG Emissions Are Relevant to Monitoring and Evaluating Quality Outcomes

The CMS Innovation Center is granted discretion to collect data necessary for the purposes of evaluating and monitoring its models under section 1115A(b)(4)(B) of the Act. Overwhelming evidence points to GHG emission's deleterious effect on patient health and the disproportionate impact born by Medicare, Medicaid, and CHIP beneficiaries. See section X.A.3.p.(1).(c).(v). of the preamble of this proposed rule, for GHG Emissions Impact on Medicare, Medicaid, and CHIP populations.

Given the established impact GHG emissions have on Medicare, Medicaid, and CHIP beneficiary health, CMS proposes to collect data on GHG emissions, through voluntary reporting, as part of our monitoring and evaluation of the model, just as CMS monitors for other quality indicators that may impact beneficiary health.

(ii) Measuring GHG Emissions is a Key First Step To Reducing GHG Emissions Which Could Improve Quality Outcomes for Beneficiaries

Measuring GHG emissions is an important first step toward reducing GHG emissions, and such reductions could lead to outcome quality improvements among beneficiaries. By organizing a GHG emissions reporting system, CMS is supporting TEAM participants in establishing a baseline understanding of their GHG emissions, how much and how efficiently energy is used in their facilities, and the emissions generated by their facilities or activities. Establishing this baseline understanding is a necessary first step to lowering emissions. The proposed decarbonization initiative could directly lead to lower emissions through: (1) sharing benchmarkable data back to TEAM participants, which will support identification of opportunities to improve energy efficiency; (2) supporting their GHG emissions reporting activities, which will support TEAM participants in better understanding their current state energy consumption, GHG emissions, and opportunities to improve energy efficiency; and (3) providing technical assistance related to reporting, identifying, and accessing resources for and undertaking activities to reduce GHG emissions.

Given the association of emissions with chronic diseases, including respiratory and cardiovascular disease, the decarbonization and resilience initiative could improve health outcomes for the Medicare, Medicaid, and CHIP beneficiaries disproportionately affected by GHG emissions. In particular, the Environmental Protection Agency (EPA) released a report on the health impacts of GHG emissions, pollution, and climate change and health and pointed towards key health outcomes that are impacted—new asthma diagnoses in children age 0–17 due to particulate air pollution, premature deaths in adults ages 65 and older due to particulate air pollution, and deaths due to extreme temperatures.[729] We would expect reductions in GHG emissions to improve these health outcomes for its patient populations.

(iii) Measuring GHG Emissions Could Improve Hospitals' Resilience and Beneficiaries' Continuity of Care, Both of Which Impact Quality Outcomes

In addition to these general health quality impacts, there are also resilience and continuity of care impacts associated with energy efficiency and a transition to sustainable energy sources for hospitals, which also impact quality outcomes. One study that examined 158 hospital evacuations between 2000 and 2017 found that nearly three-quarters were for climate-sensitive events such as wildfires or hurricanes.[730] In addition to causing hospital evacuations, climate change can disrupt health care system operations by causing facility damage and closures, power outages, displacement of health care professionals, and disruptions in transportation. These climate impacts affect access to and quality of care.

By sharing back benchmarkable data with TEAM participants (as described in section X.A.3.p.(6).(a). of the preamble of this proposed rule, Individualized Feedback Reports to TEAM Participants, of the preamble of this proposed rule), providing technical assistance related to GHG emissions reporting, and providing technical assistance to improve energy efficiency and energy resilience, the Decarbonization and Resilience Initiative could directly support TEAM participants in building greater energy resilience to disasters and ensuring greater continuity of care. We expect the Decarbonization and Resilience Initiative to increase the energy efficiency of participating TEAM participants and the degree to which they have sustainable, more localized sources of energy that are resilient to disasters and other climate change related hazards.[731] We expect this to lead to fewer hospital closures during disasters and therefore improve continuity of care and other health quality outcomes for effected beneficiaries. Greenwich Hospital offers an example of this. In 2008, the hospital invested in building a low- carbon, energy efficient energy infrastructure with the intention of it being able to withstand the impact of an extreme weather event. The investment proved to be valuable because when Hurricane Sandy hit the New Jersey coast in 2012, the hospital was still able to carry on with normal healthcare operations.

(iv) GHG Emissions are Relevant To Reducing Program Expenditures

Reductions in operating costs and spending due to energy efficiency and more efficient provision of care (in the case of anesthetic gases) directly contribute to savings for CMS. GHG

Damage in The United States: An Update. Health Affairs, vol. 39, no. 12, pp. 2071–2079. December 2020. *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01247.*

[729] EPA's Office of Atmospheric Programs. Climate Change and Social Vulnerability in the United States: A Focus on Six Impacts. U.S. Environmental Protection Agency. U.S. Environmental Protection Agency. EPA 430–R–21–003. September 2021. *https://www.epa.gov/system/files/documents/2021-09/climate-vulnerability_september-2021_508.pdf.*

[730] Sharon E. Mace & Aishwarya Sharma. Hospital Evacuations Due to Disasters in the United States in the Twenty-First Century. American Journal of Disaster Medicine, vol. 15, no. 1, pp. 7–22. January 2020, Hospital evacuations due to disasters in the United States in the twenty-first century—PubMed (*nih.gov*).

[731] NOAA Climate Program Office. Hospital Plans Ahead for Power, Serves the Community Through Hurricane Sandy. U.S. National Oceanic & Atmospheric Administration Climate Resilience Toolkit. February 15, 2018. *https://toolkit.climate.gov/case-studies/hospital-plans-ahead-power-serves-community-through-hurricane-sandy.*

emissions reporting is a necessary first step for hospitals to begin to understand their emissions, how energy efficient their facilities and processes are, and to identify opportunities to increase efficiencies and lower operating costs and spending tied to GHG emissions and to overutilization of anesthetic gas. In turn, increased energy efficiency and reduced energy expenditures may reduce Medicare Program costs. Technical assistance provided under the initiative would also further help hospitals identify, resource, and implement energy efficiency improvements.

Medicare pays Critical Access Hospitals based on each hospital's reported costs outside of IPPS. Therefore, reductions in operating costs and some capital costs could lead to cost savings for the Medicare program. Medicare pays for capital and operating costs as part of IPPS payments, and efficiencies achieved through decarbonization could lead to savings to the Medicare program. In addition, reporting questions and metrics related to energy use could improve understanding of those costs and inform potential future policy development to secure further savings.

Medicare covers anesthesia services through both Part A and Part B. Research has shown that low-flow anesthesia techniques (≤1 L/min) are associated with lower costs, reduced emissions, and do not impact quality of care or health outcomes.[732] The Patient Safety and Support of Positive Experiences with Anesthesia MIPS Value Pathway already includes an efficiency measure focused on encouraging the use of low flow inhalation general anesthesia during the maintenance phase of the anesthetic for patients aged 18 years or older who undergo an elective procedure lasting 30 minutes or longer (ABG44). Such improvements to the provision of care and anesthesia could simultaneously lower emissions and reduce costs/produce savings.

(v) GHG Emissions Impact on Medicare, Medicaid, and CHIP Populations

Medicare and Medicaid beneficiary health and program expenditures are directly impacted by GHG emissions. Older adults, or those 65 years old and older, experience poorer health outcomes because of rising temperatures, air pollution, and disaster events. Depending on global trajectories of global warming, particulate matter concentrations are estimated to result in approximately 2,000 to 6,000 premature U.S. deaths for those over 65 years old on an annual basis. Air pollution has other negative health consequences, including the exacerbation of chronic obstructive pulmonary disease and increased occurrence of heart attacks, especially for those living with diabetes or obesity.[733]

Other studies have documented the impact of weather-related events such as high temperatures, flood, storms, or hurricanes that may disproportionately affect older adults.[734] [735] [736] [737]

Medicaid beneficiaries are typically lower-income populations, pregnant people, and children, all of whom experience many direct and indirect health challenges because of climate drivers and events, including greater exposure to air pollution, mortality and injury from extreme temperatures, and food insecurity.[738]

Medicare and Medicaid beneficiaries are among the groups most vulnerable to the health effects of climate change and GHG emissions and bear the highest share of climate-sensitive health costs including those from GHG emissions which may account for billions in health-related costs to both programs.[739] [740] The Office of Management and Budget's (OMB) 2022 Assessment of the Federal Government's Financial Risks to Climate Change estimates that ''Federal climate-related healthcare spending in a few key areas could increase by between $824 million and $22 billion (2020$) by the end of the century.'' [741]

(2) Defining the Decarbonization and Resilience Initiative

We are proposing at § 512.505 that a Decarbonization and Resilience Initiative is an initiative for TEAM participants that includes technical assistance on decarbonization and a voluntary reporting program where TEAM participants may annually report questions and metrics related to emissions to CMS based on information that we describe in section X.A.3.p.(4). of the preamble of this proposed rule.

We are proposing that CMS would make available to TEAM participants technical assistance related to decarbonization, emissions reduction, and energy efficiency as described in section X.A.3.p.(4). of the preamble of this proposed rule. The voluntary reporting component of the initiative described in section X.A.3.p.(4). of the preamble of this proposed rule would allow TEAM participants to elect to report metrics including emissions data and assessment questions on four potential categories: organizational questions, building energy metrics, anesthetic gas metrics, and transportation metrics to CMS. We are proposing the building metrics would be reported to CMS using the ENERGY STAR® PortfolioManager® and all other metrics would be reported to CMS in a manner and form specified by CMS. TEAM participants that elect to report all the metrics after a performance year would receive individualized feedback reports and public recognition from CMS.

(3) Technical Assistance

For the technical assistance portion of the Decarbonization and Resilience Initiative we are proposing that CMS

[732] Alicia Edmonds, Hilary Stambaugh, Scot Pettey, & Kenn B. Daratha. Evidence-Based Project: Cost Savings and Reduction in Environmental Release With Low-Flow Anesthesia. AANA J, vol. 89, no. 1, pp. 27–33. February 2021. Evidence-Based Project: Cost Savings and Reduction in Environmental Release With Low-Flow Anesthesia—PubMed (*nih.gov*).

[733] Lulin Wang, Junqing Xie, Yonghua Hu, & Yaohua Tian. Air Pollution and Risk of Chronic Obstructed Pulmonary Disease: The Modifying Effect of Genetic Susceptibility and Lifestyle. Lancet eBioMedicine, vol. 79, pp. 103994. May 2022. Air pollution and risk of chronic obstructed pulmonary disease: The modifying effect of genetic susceptibility and lifestyle—PMC (*nih.gov*).

[734] Marina Romanello, Alice McGushin, Claudia Di Napoli, et al. The 2021 Report of the Lancet Countdown on Health and Climate Change: Code Red for a Healthy Future. Lancet, vol. 398, no. 10311, pp. 1619–1662. October 20, 2021. The 2021 report of the Lancet Countdown on health and climate change: code red for a healthy future—The Lancet.

[735] Janet L. Gamble & John Balbus. Chapter. 9: Populations of Concern. In: U.S. Global Change Research Program. The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment. 2016. The Impacts of Climate Change on Human Health in the United States: A Scientific Assessment (*globalchange.gov*).

[736] Diarmid Campbell-Lendrum & Nicola Wheeler. COP24 Special Report: Health & Climate Change. World Health Organization Special Report. 2018. 9789241514972-eng.pdf (*who.int*).

[737] Laura P. Sands, Quyen Do, Pang Du, Yunnan Xu, & Rachel Pruchno. Long Term Impact of Hurricane Sandy on Hospital Admissions of Older Adults. Social Science & Medicine, vol. 293, pp. 114659. January 1, 2023. Long term impact of Hurricane Sandy on hospital admissions of older adults—PMC (*nih.gov*).

[738] Wim Thiery, Stefan Lange, Joeri Rogel, et al. Intergenerational Inequities in Exposure to Climate Extremes. Science, vol. 374, no. 6564, pp. 158–160. September 26, 2021. Intergenerational inequities in exposure to climate extremes—PubMed (*nih.gov*).

[739] Vijay S. Limaye, Wendy Max, Juanita Constible, & Kim Knowlton. Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012. GeoHealth, vol. 3, no. 9, pp. 245–265. September 17, 2019. Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012—PMC (*nih.gov*).

[740] Ibid.

[741] U.S. Office of Management & Budget. Climate Risk Exposure: An Assessment of the Federal Government's Financial Risks to Climate Change. OMB White Paper. April 2022. *https://www.whitehouse.gov/wp-content/uploads/2022/04/OMB_Climate_Risk_Exposure_2022.pdf.*

would provide three types of support to interested TEAM participants:

- Developing approaches to enhance organizational sustainability and resilience;
- Transitioning to care delivery methods that result in lower GHG emissions and are clinically equivalent to or better than previous care delivery methods (for example, switching from Desflurane to alternative inhaled anesthetics); and
- Identifying and using tools to measure emissions and associated measurement activities.

In the first support type, developing organizational approaches, CMS would entail offer interested TEAM participants guidance on best practices and methods for identifying opportunities to reduce GHG emissions while promoting sustainability and resilience. Particular attention will be placed on building efficiency and sustainable transportation. We would also help to identify potential non-Medicare financing strategies for this work, noting that TEAM participants have access to tax credits and grant programs that can support decarbonization and climate resilience investments through the Inflation Reduction Act,[742] as well as other federal funding opportunities.[743] OCCHE is leading a Catalytic Program to support safety-net health providers in taking advantage of these unprecedented opportunities; TEAM participants would be encouraged to take advantage of the recorded content and other materials from that program.[744]

With respect to the second type of support transitioning to lower-carbon clinical alternatives, we would offer guidance on strategies for reducing emissions associated with inhaled anesthetic gases in pursuit of improvements on the measures described later in this section (drawing in part on ongoing work by federal health systems in this area). Other types of care delivery transitions could benefit patients by reducing demand for hospital services through education, addressing health inequities, improving telehealth options, and improving upstream care management.

For the third type of support, developing emissions measurement strategies, we would identify relevant measures, existing tools (for example, the ENERGY STAR Portfolio Manager platform described in section X.A.3.p.(4). of the preamble of this proposed rule) and new tools as needed. We would also offer guidance on strategies for using emissions data to identify opportunities to save energy and reduce emissions (for example, ENERGY STAR® Treasure Hunt to identify potential areas to reduce energy usage).[745]

We are proposing that this technical assistance would be targeted to interested TEAM participants, but we would also make this information available to other hospitals that might request it, as feasible.

(4) Voluntary Reporting

For the voluntary reporting portion of the TEAM Decarbonization and Resiliency Initiative, we are proposing at § 512.598 that TEAM participants may elect to report metrics and questions related to emissions to CMS on an annual basis following each performance year. TEAM participants that elect to report on all the initiative metrics and questions to CMS, in the form and manner required by CMS, would be eligible for benefits such as receiving individualized feedback reports and public recognition as well as potentially achieving operational savings (please note these savings would be incidental and not a result of model-related payments). In section X.A.3.p.(4). of the preamble of this proposed rule, we propose the metrics and questions that would be included in the voluntary reporting initiative. In section X.A.3.p.(5). of the preamble of this proposed rule, we propose how and when the metrics and questions would be reported to CMS. Finally, in section X.A.3.p.(6). of the preamble of this proposed rule, we outline our proposals for benefits for TEAM participants that elect to engage in the voluntary reporting portion of the Decarbonization and Resiliency Initiative as well as document some potential indirect benefits, such as operational savings.

(a) Decarbonization and Resilience Initiative Metrics

(i) Background on Scope and Metrics Sources

As discussed in section X.A.3.p.(1). of the preamble of this proposed rule, the GHGP establishes a framework for measuring Scope 1 and Scope 2 emissions. In identifying priority Scope 1 and Scope 2 categories and metrics for emissions reporting for TEAM participants, we considered guidance and research from several sources. In 2022, AHRQ convened an expert panel to develop a primer for identifying, prioritizing, monitoring, and reducing health care carbon emissions. In developing our proposals, we referred to this AHRQ primer to identify potential measures for Scopes 1 and 2. We also looked at guideline sources, such as the new Sustainable Healthcare Certification requirements by The Joint Commission (TJC), for their elements on leadership, measurement, and performance improvement; and guidance from the National Academy of Medicine (NAM) for steps and key actions to reduce GHG emission within health care systems.

The AHRQ primer identified three categories that fit into Scopes 1 and 2: building energy, anesthetic gases, and transportation. NAM published key actions that facilities could take to address greenhouse gas emissions.[746] These actions are broken into two steps. Step I focuses on actions to start a decarbonization journey and includes activities like assembling an executive sustainability team, performing a GHG inventory, and establishing specific decarbonization goals. Step II actions, which focus on specific interventions, include activities for reducing emissions from building energy, anesthetic gas, and transportation. TJC launched a Sustainable Healthcare Certification program that includes required standards for organizational performance and leadership, such as a sustainability plan, as well as requirements for collection of detailed emissions information for at least 3 different sources out of six—energy use (fuel combustion), purchased electricity

[742] HHS Office of Climate Change & Health Equity. (OCCHE) Quickfinder for Leveraging the Inflation Reduction Act for the Health Sector. HHS Office of the Assistant Secretary for Health. February 27, 2024. The Office of Climate Change and Health Equity (OCCHE) Quickfinder for Leveraging the Inflation Reduction Act for the Health Sector | *HHS.gov*.

[743] HHS Office of Climate Change & Health Equity. Compendium of Federal Resources for Health Sector Emissions Reduction and Resilience. HHS Office of the Assistant Secretary for Health. December 7, 2023. Compendium of Federal Resources for Health Sector Emissions Climate Change Technical Assistance for Territories Reduction and Resilience | *HHS.gov*.

[744] HHS Office of Climate Change & Health Equity. Catalytic Program on Utilizing the IRA. HHS Office of the Assistant Secretary for Health Resource Hub. March 1, 2024. *https://www.hhs.gov/climate-change-health-equity-environmental-justice/climate-change-health-equity/health-sector-resource-hub/new-catalytic-program-utilizing-ira/index.html*.

[745] Energy Star Treasure Hunts, *https://www.energystar.gov/industrial_plants/treasure_hunt*.

[746] Kathy Gerwig, Hardeep Singh, Jodi Sherman, Walt Vernon, & Beth Schenk. Action Collaborative on Decarbonizing the Health Sector. Key Actions to Reduce Greenhouse Gas Emissions by U.S. Hospitals and Health Systems. National Academy of Medicine Climate Collaborative. 2022. *https://nam.edu/programs/climate-change-and-human-health/action-collaborative-on-decarbonizing-the-u-s-health-sector/key-actions-to-reduce-greenhouse-gas-emissions-by-u-s-hospitals-and-health-systems/*.

(purchased grid electricity, district steam, chilled and hot water), anesthetic gas use (including volatile agents and nitrous oxide), pressurized metered-dose inhaler use), fleet vehicle carbon-based fuel use (from organization-owned vehicles), and waste disposal.

(ii) Proposed Scope and Sources for Metrics

At this time, we are proposing to limit metrics that TEAM participants may voluntarily report for the Decarbonization and Resilience Initiative to Scope 1 (direct emissions related to health care operations) and Scope 2 (emissions related to purchased electricity consumption). We believe that TEAM participants have more ability to track and report these metrics at this time and could use information from these metrics to assess ways to reduce their carbon emissions and improve their operating efficiency. TEAM participants would be encouraged to look at emissions across all three Scopes, but for this initial program, the proposed metrics would include Scopes 1 and 2. We seek comment on our proposal to limit the focus of the Decarbonization and Resilience Initiative to Scopes 1 and 2 for the initial years of the TEAM Model.

Based on programs and publications discussed in section X.A.3.p.(4).(a).(i). of the preamble of this proposed rule, we are proposing four areas for reporting: (1) Organizational Questions; (2) Building Energy Metrics; (3) Anesthetic Gas Metrics; and (4) Transportation Metrics. We are proposing at § 512.598(a) the metrics for the voluntary program. TEAM participants, if they so choose, would report on these four categories. In proposing these voluntary questions and areas for voluntary metric reporting, CMS is prioritizing alignment with existing initiatives such as those described in section X.A.3.p.(4).(a).(i). of the preamble of this proposed rule.

(iii) Organizational Questions

For the Decarbonization and Resilience Initiative, we are proposing at § 512.598(a)(1) a set of organizational questions about the TEAM participants' sustainability team and sustainability activities. These questions are generally based on NAM's key action Step I shortlist. We propose the organizational questions would include the following:

- Does your facility have a sustainability team? If so, does your facility's sustainability team include broad representation, seeking input across operational and clinical lines, and engaging staff, executive leaders, clinicians, board members, and patients?
- Does your facility perform a GHG inventory? If so, which of the following are included in your facility's GHG inventory:
  - ++ Scope 1 emissions.
  - ++ Scope 2 emissions.
  - ++ Scope 3 emissions (business travel, employee commuting, waste)?
- Has your facility implemented a decarbonization goal that compares performance to a baseline year?
- What are your facility's decarbonization goals (for example, 10 percent GHG reduction annually across all operations, aiming to achieve 50 percent reduction by 2030)? What is the baseline year used to measure your facility's decarbonization success?
- Has your facility implemented a decarbonization plan?
- What is your facility's implementation plan? What milestones and deliverables to track progress are you documenting?
- Has your facility designated resources for decarbonization and resilience initiatives?
- Does your facility track operation room (OR) specific energy use or waste? If so, what, if any, OR energy efficiency or waste reduction initiatives have you implemented?

We anticipate these questions would be relatively straightforward to report on and may encourage TEAM participants who that have not yet started working on decarbonization and/or resilience initiatives to see what other hospitals are doing to implement decarbonization efforts. We seek feedback on the potential burden of adding overall organizational questions to the Decarbonization and Resilience Initiative.

(iv) Building Energy Metrics

For building energy usage, we are proposing metrics that would assess both the raw GHG emissions (location-based and market-based methods of calculation) from energy use (direct and indirect), source information, and information to normalize these metrics. Specifically, we are proposing at § 512.598(a)(2) a set of building energy metrics related to measuring and reporting GHG emissions related to energy use at TEAM participant facilities. We are proposing at § 512.598(a)(2)(i) that these proposed building energy metrics would be based on the ENERGY STAR® Portfolio Manager® guidelines for the time of submission and that TEAM participants choosing to report these metrics must submit using ENERGY STAR® Portfolio Manager® according to the reporting and timing requirements proposed in section X.A.3.p.(5). of the preamble of this proposed rule. We are proposing to adopt the ENERGY STAR® Portfolio Manager® guidelines at the time of submission to ensure that the metrics collected are consistent with current standards.

For the Decarbonization and Resilience initiative, we are proposing at § 512.598(a)(2)(ii) the following metrics: ENERGY STAR® Score for Hospitals, as well as the supporting data that goes into that calculation, and energy costs and basic energy consumption metrics such as total, direct, and indirect GHG emissions and emissions intensity as specified in the ENERGY STAR® Portfolio Manager®.[747] As of this publication, the most recent ENERGY STAR® Score for Hospitals methodology was published in February 2021[748] and requires information such as energy use intensity, electricity, natural gas, and other source emissions usage and several normalizing factors such as building size, number of full-time equivalent workers, number of staffed beds, number of magnetic resonance imaging (MRI) machines, and zip code (to pull weather and climate related data such as the number of heating and cooling days).[749] We propose that this supporting data would be reported to CMS, as well. Having both the aggregate score and the underlying details would provide CMS additional detail to monitor the impact of emissions. As described in section X.A.3.p.(5). of the preamble of this proposed rule, TEAM participants who elect to report data would submit after the performance year. Should the ENERGY STAR® Score for Hospitals method change, we would default to the methods that ENERGY STAR® is using at the time of submission so that the data reported to CMS would be consistent with ENERGY STAR® Score for Hospitals.

ENERGY STAR® Portfolio Manager® also allows users to track GHG

[747] EPA Office of Air Programs. ENERGY STAR Portfolio Manager Glossary. U.S. Environmental Protection Agency & U.S. Department of Energy. Undated. *https://portfoliomanager.energystar.gov/pm/glossary.*

[748] EPA Office of Air Programs. ENERGY STAR Score for Hospitals (General Medical and Surgical). U.S. Environmental Protection Agency & U.S. Department of Energy. February 19, 2021. *https://www.energystar.gov/buildings/tools-and-resources/energy-star-score-hospitals-general-medical-and-surgical.*

[749] EPA Office of Air Programs. Technical Reference: ENERGY STAR Score for Hospitals in the United States. U.S. Environmental Protection Agency & U.S. Department of Energy. February 2021. *https://www.energystar.gov/sites/default/files/tools/Hospital_TechnicalReference_Feb2021_508.pdf.*

emissions and energy costs, which captures total energy cost and can inform tracking of potential savings.

There are several reasons we are proposing that TEAM participants use the ENERGY STAR® Portfolio Manager® for submitting building energy metrics. First, ENERGY STAR® Portfolio Manager® is a free, on-line benchmarking tool used by over 3,000 hospitals as of January 2024 (approximately half of the number of U.S. hospitals [750]) to benchmark energy, water, and waste. Approximately forty-seven state and local governments [751] require its use to track and report energy usage and emissions on an annual basis. We believe that by using data and information collected in the ENERGY STAR® Portfolio Manager® tool, we would minimize the reporting burden for TEAM participants and maximize the benchmarking value of reporting, which should make comparisons and measuring progress easier. We also believe the information collected in the ENERGY STAR® Score for Hospitals are similar to recommended measures in the AHRQ primer.

Finally, we also considered an alternative where we instead allowed private vendors with a relationship to the facility to submit equivalent information, aligned to the GHG Protocol, instead of ENERGY STAR Portfolio Manager. Ideally, we would like TEAM participants to have options to collect and capture their emissions data, but we also want to ensure that any benchmarks are consistent across TEAM participants.

We seek feedback on our proposed metrics reported through ENERGY STAR Portfolio Manager and on the alternative of allowing private vendors to submit equivalent information.

(v) Anesthetic Gas Metrics

We believe anesthetic gas metrics are important to collect for the TEAM Decarbonization and Resilience Initiative because the TEAM's proposed initial performance focus is on surgical procedures which regularly utilize anesthetic gas, as discussed previously. We are proposing at § 512.598(a)(3) a set of metrics related to measuring and managing emissions from anesthetic gas. These metrics include total GHG emissions from inhaled anesthetic gasses (based on purchase records) along with the associated normalization factors, and additional assessment questions.

We evaluated methods to consistently capture anesthesia metrics. ENERGY STAR Portfolio Manager currently does not collect information or calculate benchmarks on anesthetic gases. There are other calculators, such as Practice Greenhealth's ® Health Care Emissions Impact Calculator that collect and calculate data related to anesthetic metrics,[752] but we were concerned that using multiple tools to report metrics (considering we are already proposing to use ENERGY STAR® Portfolio Manager® for the building energy metrics) would increase reporting complexity and reporting burden. The AHRQ primer recommended total GHG emissions from inhaled anesthetics and mean gas flow rates, but we were concerned on the feasibility of capturing mean gas flow rates. Based on all these factors, we are therefore proposing at § 512.598(a)(3)(i) to include a metric for total GHG emissions from inhaled anesthetics using purchased records. The metric would include information such as volume of the bottle, the number of bottles, and/or the number of pounds, depending on the anesthetic gas.[753] We believe purchase records provide a proxy for actual utilization and that purchased records may be easier for TEAM participants to report compared to actual usage which generally would have to be extracted from electronic health records. Also, we are proposing at § 512.598(a)(3)(ii) normalization factors which we propose to be anesthetic hours so we could more accurately compare the carbon impact across different facilities. We believe these metrics would provide information on anesthetic gases which would be most relevant to the episodes and provide a means for which to create anesthetic gas metric benchmarks.

At § 512.598(a)(3)(iii), we are also proposing to include assessment questions broadly based on the key actions recommended by NAM Step II for reducing emissions from anesthetic gases that TEAM participants may choose to answer. Assessment questions include the following:

- Has your facility set an emissions reduction goal related to anesthetic gases?
- Does your facility track and benchmark anesthetic gas emissions at the procedure and provider level?
- Has your facility removed the use of desflurane or removed vaporizers when using desflurane?
- Has your facility decommissioned piped nitrous oxide and substituted e-cylinders? If not, are these activities in process?

We believe answering these assessment questions would provide facilities with ideas and actions that could in turn reduce impact on emissions and would supplement the other anesthesia gases data.

We seek comment on our proposed anesthesia gas metrics which would include the total GHG emissions from inhaled anesthetics and anesthetic hours and assessment questions for anesthetic gases. We particularly seek feedback on the feasibility of reporting data based on purchase records or whether we should require actual records. We also seek comment on the feasibility of capturing anesthetic hours or if we should consider a different normalization factor such as number of operating rooms. We are also seeking feedback on whether we should consider other calculators, metrics and inputs to determine GHG emissions from anesthetic gases, or quality measures such as ABG44: Low Flow Inhalational General Anesthesia.

Finally, while we believe it is important to capture the data on total GHG emissions from inhaled anesthetics, anesthetic hours, and the assessment questions for anesthetic gases, we also considered whether we provide the TEAM participants an option of reporting either the total GHG emissions from inhaled anesthetics (with anesthetic hours) or reporting the assessment questions for the voluntary reporting program. We believe this flexibility for TEAM participants could reduce reporting burden and enhance participation, but we are concerned this alternative may not provide comparable data across the TEAM participants who voluntarily submit data. We seek feedback on this alternative for TEAM participants who choose to submit to report either anesthetic gases and anesthetic hours or to report the assessment questions.

(vi) Transportation Metrics

The third category of information relevant to health care facilities is the GHG emissions related to leased or owned vehicles. We are proposing at § 512.598(a)(4) a set of metrics that focus on greenhouse gases related to leased or owned vehicles. We are proposing § 512.598(a)(4)(i) through (a)(4)(iii)

[750] AHA Health Forum. Fast Facts on Hospitals. American Hospital Association. 2024. *https://www.aha.org/statistics/fast-facts-us-hospitals.*

[751] EPA Office of Air Programs. State/Local Compliance Ordinances. U.S. Environmental Protection Agency & U.S. Department of Energy. February 20, 2024. State/local compliance ordinances (*site.com*).

[752] Practice Greenhealth. Health Care Emissions Impact Calculator. 2023. *https://practicegreenhealth.org/tools-and-resources/health-care-emissions-impact-calculator.*

[753] We recognize that certain gases and compounds are most easily measured by volume and others in weight as they are not purchased by bottle (for example, Nitrous Oxide).

metrics that include gallons for owned and leased vehicles consistent with GHGP Scope 1 requirements, patient encounter volume as a normalization factor, and assessment questions. For transportation emissions related to patient transportation and supply chain, please see the RFI on Scope 3 emissions which seeks comment on the feasibility of reporting Scope 3 emissions such as those from Scope 3 transportation emissions (for example, patient transportation).

Including information on gallons for owned and leased vehicles aligns with the AHRQ primer core measure for transportation, and we anticipate that TEAM participants can capture this information. We also propose that if TEAM participants choose to partake in the Decarbonization and Resilience Initiative Voluntary Reporting, we would require TEAM participants to capture patient encounter volume as a normalization factor and are considering a range of other factors consistent with GHG protocols such as full-time equivalents (FTEs).

We are also proposing a series of assessment questions that align with the NAM recommended key actions to reduce transportation emissions. Assessment questions include the following:

- Has your facility set an emissions reduction goal related to transportation?
- Has your facility executed plans to reduce fleet emissions (either from reducing miles or replacing with electric vehicles [EVs])?
- Has your facility identified measures to optimize product delivery?
- Has your facility provided (or in the process of providing) EV charging infrastructure?

We seek feedback on the proposed transportation metrics. Additionally, we seek feedback to the extent hospitals are tracking this information and the operational feasibility to track and report this information or if other alternative metrics may be more feasible (for example, mileage). Finally, while we believe it is important to capture both the data on the gallons of gas as well as the assessment questions, we also considered whether we provide the TEAM participants an option of reporting either the gallons data or reporting the assessment questions for the voluntary reporting program. We believe this flexibility for TEAM participants could reduce reporting burden and enhance participation, but we are concerned this alternative may not provide comparable data across the TEAM participants who voluntarily submit data. We seek feedback on this alternative for TEAM participants who choose to submit to report either gallons and patient encounter or to report the assessment questions.

(vii) Request for Information on Scope 3 Metrics and MDIs

Both Scope 3 and MDI emissions account for a large percentage of medical carbon emissions and CMS is interested in potential ways in which to provide technical assistance to TEAM participants to assess available metrics to help reduce the enormity of this impact.

(a) Scope 3 Metrics

We believe Scope 3 emissions are relevant to a Decarbonization and Resilience Initiative connected to TEAM because Scope 3 emissions account for 82 percent of all U.S. health care emissions. Scope 3 includes all emissions upstream and downstream in the supply chain and other indirect emissions. We seek additional information regarding potential future voluntary reporting of Scope 3 emissions.

- What metrics or data collection elements would be appropriate for TEAM participants to accurately report Scope 3 emissions?
- Is there an industry standard tool that can be utilized for Scope 3 reporting?
- Which Scope 3 categories are most feasible and appropriate for hospitals participating in TEAM to report at this time?
- How can CMS and hospitals engage other parts of supply chain that contribute to Scope 3 emissions or incentivize their reduction of Scope 3 GHGs?
- Would hospital burden of Scope 3 reporting differ from Scope 1 and 2 reporting?

(b) MDIs

Also, under Scope 3, we seek additional information regarding MDIs. We believe that further understanding of the MDI prescription and usage rates could assist in finding pathways of reduction and substitution to a less harmful environmental option. However, we understand that most MDI prescriptions and the management of related conditions occur in the outpatient setting and may not be directly relevant to TEAM participants. Hospital reductions in MDI prescriptions can still result in significant reductions of GHG emissions. For example, Providence Oregon hospitals identified clinically equivalent MDI formulations of albuterol with 3-fold differences in emissions.[754] By prioritizing the lower emissions intensity inhalers, these emissions are projected to drop by 42 percent, or 298 tons of CO2e (the equivalent of 64 gasoline powered passenger vehicles driven) per year. We are seeking information on the feasibility of capturing information on MDI outpatient prescriptions as a percentage of all inhaler prescriptions relevant to TEAM participants.

- What role do acute care hospitals, hospital-based pharmacies, or other providers in the inpatient setting play in prescribing MDIs and guiding patients toward environmentally preferable selections, such as dry powder inhaler,[755] when clinically safe to do so?

We believe it would be important to record data such as the volume of each MDI cannister (micrograms) and number of MDI cannisters prescribed on an annual basis and this would be helpful to capture. We are seeking feedback on the feasibility of capturing information for the following questions:

- What is the utilization rate of MDIs and dry powder inhalers, for inpatients?
- What is the prescription rate of MDIs and dry powder inhalers?
- Is there a way to replace the MDI propellant from a hydrofluorocarbon to hydrofluoroalkane?

(5) Report Timing

For the Decarbonization and Resilience Initiative, we are proposing at § 512.598(b) that if TEAM participants so choose, they would report information annually to CMS after each performance period. The form and manner would be specified by CMS for each performance period including using ENERGY STAR® Portfolio Manager® for building energy metrics proposed in section X.A.3.p.(4).(a).(iv). of the preamble of this proposed rule. We anticipate reporting for the other metrics and assessment questions would be a survey and questionnaire in a form and manner specified by CMS. We are also proposing at § 512.598(b) that the Decarbonization and Resilience Initiative information would need to be reported to CMS by no later than 120 days in the year following the

[754] Bhargavi Sampath, Matthew Jensen, Jennifer Lenoci-Edwards, Kevin Little, Hardeep Singh, & Jodi D. Sherman. Reducing Health care Carbon Emissions: A Primer on Measures and Actions for Health Care Organizations to Mitigate Climate Change. U.S. Agency for Healthcare Research & Quality. AHRQ pub. No. 22–M011. September 2023. Reducing Healthcare Carbon Emissions: A Primer on Measures and Actions to Mitigate Climate Change (*ahrq.gov*).

[755] Kimberly Wintemute & Fiona Miller. Dry Powder Inhalers Are Environmentally Preferable to Metered-Dose Inhalers. CMAJ, vol. 192, no. 29, pp. E846. July 20, 2020. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7828988/*.

performance period, or a later date as determined by CMS. We believe it is important to have flexibility to delay the reporting in case of an emergency or technical issue.

We also considered requiring reporting by June 1 after the performance period to align with the majority of the local decarbonization programs that report to ENERGY STAR®.[756] We are seeking comment on the proposed report timing and alternatives.

(6) Benefits for TEAM Participants Who Elect To Report in the Decarbonization and Resiliency Initiative

We are proposing at § 512.598(c) that TEAM participants who elect to report all the metrics identified in section X.A.3.p.(4). of the preamble of this proposed rule in the manner described in section X.A.3.p.(5). of the preamble of this proposed rule would receive individualized feedback reports and be eligible to receive public recognition for their commitment to decarbonization. In addition to these proposed benefits, we believe TEAM participants may receive additional indirect benefits from engaging in the voluntary reporting portion of the Decarbonization and Resiliency Initiative.

(a) Individualized Feedback Reports to TEAM Participants

We are proposing at § 512.598(c)(1) to provide individualized feedback reports to TEAM participants who voluntarily report to CMS the four emissions-related metrics in the Decarbonization and Resilience Initiative. We anticipate these reports would summarize facilities' emissions metrics and would include benchmarks, as feasible, for normalized metrics to compare facilities, in aggregate, to other TEAM participants in the Decarbonization and Resilience Initiative. While ENERGY STAR has many robust benchmarks related to building energy efficiency, we believe that TEAM participants would be able to learn additional information from peers about emissions from anesthetic gases and transportation emissions. See section X.A.3.p.(4).(a). of the preamble of this proposed rule for discussion of the proposed metrics and calculator tools to be used as part of the Decarbonization and Resilience Initiative. CMS does not intend to make these individualized feedback reports available to the public or other TEAM participants and intends them for the purpose of learning and improvement.

We invite public comment on this proposal.

(b) Establishment of a Publicly Reported Hospital Recognition of Decarbonization Commitment

We propose at § 512.598(c)(2) to establish a publicly reported hospital recognition badge for the TEAM participant's commitment to decarbonization; CMS would post a hospital recognition badge on a CMS website. We would provide annual recognition to TEAM participants for reporting all the metrics detailed in section X.A.3.p.(4).(a). of the preamble of this proposed rule. The recognition badge would be reevaluated each year based on the reporting of performance year metrics to CMS. We believe adding this recognition to a consumer-facing CMS website would allow patients and families to choose hospitals that have participated in efforts to measure health care carbon emissions.

To encourage meaningful reductions in emissions, we are seeking comments on potentially expanding to a tiered recognition in future years. We believe a tiered approach could better acknowledge TEAM participants that have elected to voluntarily report their emissions data, actively engage in decarbonization activities that would result in reduced Scopes 1, 2, and 3 emissions, and meet absolute or relative standards of reported energy efficiency and lowered emissions. We seek comment on tiering such badging so as to recognize TEAM Participants that meet certain absolute or relative standards based on emissions reporting measures or other standards such as the Department of Energy's National Definition for a Zero Emission Building and may consider making select reported information public.[757] Any modifications to the public recognition benefit would be addressed through future rulemaking.

We invite public comment on the proposed publicly reported hospital recognition of decarbonization commitment.

(c) Indirect Benefits

We believe that in addition to the direct benefits of participating in the Decarbonization and Resilience Initiative there are several indirect benefits associated with the Initiative's efforts to assist interested TEAM participants in undertaking decarbonization and resilience activities. Decarbonization can help improve the financial well-being of health care facilities by reducing operational costs. Estimates indicate that up to 30 percent of the energy used in hospitals and other commercial buildings is consumed unnecessarily and investing in decarbonization has been shown to decrease operational costs through supply chain optimization and reduced energy consumption and expenditures.[758]

Beyond the potential cost reduction benefit of decarbonization, investing in decarbonization may help to improve patient care and outcomes. For example, facilities that opt to reduce GHG emissions by switching to renewable energy sources increase their resilience and thus can bypass power outages in the electric grid during climate emergencies. Furthermore, by reducing GHG emissions, healthcare facilities are contributing to preventing or ameliorating adverse health outcomes that are linked to air pollution and climate change-related hazards like hurricanes (for example, respiratory illnesses, injury).[759] Health systems could benefit patients by reduced demand for hospital services through encouraging health education, addressing health inequities perpetuated by social determinants of health, improving telehealth options, and improving upstream care management. A well-developed sustainability strategy could allow health systems to become more resilient to the consequences of extreme weather events, which exacerbate patients' chronic cardiac, respiratory, and other conditions.[760]

[756] EPA Office of Air Programs. State/Local Compliance Ordinances. U.S. Environmental Protection Agency & U.S. Department of Energy. February 20, 2024. State/local compliance ordinances (*site.com*).

[757] Kent Peterson, Paul Torcellini, & Roger Grant. A Common Definition for Zero Energy Buildings. National Institute of Building Sciences. September 2015. DOE/EE–1247. *https://www.energy.gov/sites/default/files/2015/09/f26/bto_common_definition_zero_energy_buildings_093015.pdf*.

[758] Hardeep Singh, Walt Vernon, Terri Scannell, & Kathy Gerwig. (2023). Crossing the Decarbonization Chasm: A Call to Action for Hospital and Health System Leaders to Reduce Their Greenhouse Gas Emissions. National Academy of Medicine Discussion Paper. November 29, 2023. *https://nam.edu/crossing-the-decarbonization-chasm-a-call-to-action-for-hospital-and-health-system-leaders-to-reduce-their-greenhouse-gas-emissions/*.

[759] Vijay S. Limaye, Wendy Max, Juanita Constible, & Knowlton. Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012. GeoHealth, vol. 3, no. 9, pp. 245–265. September 17, 2019. Estimating the Health-Related Costs of 10 Climate-Sensitive U.S. Events During 2012—PMC (*nih.gov*).

[760] The Joint Commission. Sustainable Healthcare Certification. 2024. Sustainable Healthcare Certification | The Joint Commission.

(d) Request for Information on Potential Future Incentives for Participation in the Voluntary Decarbonization and Resilience Initiative

At this time, we are not proposing any bonuses, payments, or payment adjustments to TEAM participants for voluntary reporting in the Decarbonization and Resilience Initiative. We may add such a policy to the Decarbonization and Resilience Initiative in future years, subject to additional rulemaking. We seek feedback on the ways we could structure potential payments, bonuses, or payment adjustments. To offer some examples:

- A potential bonus added to the Composite Quality Score (CQS), which is discussed in section X.A.3.d.(5).(e). of the preamble of the proposed rule, for TEAM participants who report the information for the Decarbonization and Resilience Initiative. This would reward TEAM participants for collecting and reporting data, but not necessarily for better performance.
- We could elect to modify the CQS score by providing a bonus for those who perform well on the Decarbonization and Resilience Initiative. We welcome thoughts on which metrics we should identify for measuring performance and how a bonus could be structured.

We invite public comment on the future bonuses, payments, or adjustments for participation in the Decarbonization and Resilience Initiative.

q. Termination of the TEAM

The general provisions relating to termination of the model by CMS in 42 CFR 512.596 would apply to the TEAM. Consistent with these provisions, in the event we terminate the TEAM, we would provide written notice to TEAM participants specifying the grounds for termination and the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and § 512.594, termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

B. Provider Reimbursement Review Board (PRRB) (§ 405.1845)

Section 1878 of the Act (42 U.S.C. 1395oo) established by the Social Security Amendments of 1972, describes the role and function of the Provider Reimbursement Review Board (PRRB), a five-member administrative tribunal that adjudicates disputes over Medicare reimbursement for certain providers of services in the Medicare program. The statute requires the HHS Secretary to appoint individuals to the PRRB for a 3-year term of office; the law also established a shorter length of office for the first appointments for the newly created PRRB to permit staggered terms of office. To qualify for appointment to the PRRB, all members must be knowledgeable in the field of payment of providers of services; two members must be representative of a Medicare provider of services; and at least one member must be a certified public accountant. In 1974, the Social Security Administration (SSA), which administered the Medicare program prior to its transfer to the Health Care Financing Administration in the Department of Health and Human Services, promulgated the implementing regulations for the PRRB. The regulations governing the operation and administration of the PRRB reside at 42 CFR part 405 subpart R, with the provision governing the composition of the PRRB at 42 CFR 405.1845. In addition to codifying the statutory requirements governing the composition of the PRRB, the regulations established that no Board Member is permitted to serve more than two consecutive 3-year terms of office and that the Secretary has the authority to terminate a Board Member's term of office for good cause.

When the PRRB was established more than 50 years ago, payment to providers participating in the Medicare program was on a cost reimbursement basis. Beginning October 1, 1983, Medicare transitioned to a prospective payment system for inpatient hospitals. These changes in reimbursement have led to changes in the types of cases adjudicated by the Board, the complexity of the matters that come before the Board, and often, the amount of time required to bring matters to resolution. While the limit on the number of consecutive terms served by a Board Member was established in the 1974 implementing regulations, CMS no longer believes that the current limitation on the number of consecutive terms a Board Member may serve makes good sense.

In this proposed rule, we propose to amend paragraphs (a) and (b) of 42 CFR 405.1845, effective January 1, 2025.

- First, we seek to modify the requirement that Board Members shall be knowledgeable in the area of cost reimbursement, so that it instead requires them to be knowledgeable in the field of payment of providers under Medicare Part A.
- Second, we propose to permit a Board Member to serve no more than three consecutive terms, instead of two consecutive terms allowed under current regulations.
- Third, we propose to permit a Board Member who is designated as Chairperson in their second or third consecutive term to serve a fourth consecutive term to continue leading the Board as Chairperson.

The proposed change to paragraph (a) is intended to align the regulatory language with the statute, which, at section 1878(h) of the Act states, ''All of the members of the Board shall be persons knowledgeable in the field of payment of providers of services . . .'' As explained earlier in this preamble, it was the case that Medicare payment to providers was on cost reimbursement basis when this provision became law; however, this change would clarify that a Board Member must have knowledge of Medicare Part A payment (which broadly covers the category of cases adjudicated by the PRRB, as opposed to the narrower subcategory of cost reimbursement matters). The proposed changes to paragraph (b) are intended to reduce the amount of turnover that occurs on the PRRB, enabling CMS to recruit and retain highly qualified individuals as they gain experience in adjudicating cases. We believe that these changes have the potential to expand the pool of applicants seeking to serve on the Board and who, because of the current two-term limitation, may not be willing to entertain a job change for what would be at most a 6-year period of service. These changes would also create a new pathway for advancement for an experienced Board Member to continue their service to the PRRB in the Chairperson position. Under current regulations, if a Board Member is serving in their first or second consecutive term and later designated as Chairperson, the total length of service on the PRRB remains 6 years, or two consecutive terms. In other words, a Board Member who is designated as Chairperson in year 4 or 5 of their second consecutive term is only permitted to serve 1 to 2 more years as Chairperson. Under this proposal, the PRRB would continue to benefit from having an experienced Board Member serve for a total of 12 years, if they were designated as Chairperson in their second or third consecutive term.

We recognize that the limit of two consecutive terms under current regulations creates more openings on the PRRB, which offers opportunities for newly appointed individuals to apply their unique skill sets, experience, and perspective to the work. However, there is an opportunity cost associated with the current level of turnover. Recruitment of Board Members occurs

with regularity, generally every 1 to 3 years, and considerable time and effort have been expended by CMS and HHS in recruiting and vetting candidates as well as training newly appointed Board Members. Over time, it has been increasingly challenging to attract a large pool of qualified candidates who have relevant skills and experience in matters that come before the PRRB.

Even after a candidate is identified, they must be formally appointed to the PRRB by the Secretary. Upon accepting the appointment, a Board Member must devote significant time to learning the duties of the job. As a result, in our experience, a newer Board Member takes more time to complete tasks relative to their colleagues who have more experience in the role. While Board Members may have a strong legal, accounting, health care, or other professional background, this position often is the first time they are in an adjudicatory role. Conversely, when a Board Member departs, there is a loss of institutional knowledge and expertise that adversely impacts efficiency and productivity. Turnover also impacts the relationships among and between the Board Members, and it takes time for the newly constituted Board to learn how to work together. This proposal would decrease the frequency of turnover and permit lengthier periods of service for Board Members, which we believe would have the potential to increase the PRRB's efficiency and productivity.

The volume of cases filed with the PRRB has remained relatively steady over the past several decades with the average number of appeals filed and closed annually hovering around 2,000. The PRRB's docket has experienced years in which fewer appeals were filed in large part due to holds on issuing Notices of Program Reimbursement from which many providers file their appeals. A year or years with a lower appeals volume was then followed in subsequent years by spikes of new appeals once the holds were lifted. The PRRB's total docket has ranged from about 5,000 appeals to about 10,000 appeals over the last 30 years, with an average ending annual inventory of 8,700 cases. The PRRB's fiscal year 2023 docket ended with 8,698 open appeals.

Additionally, the nature of the PRRB's cases has evolved. For example, in the past decade, the PRRB has seen an increase in broad-based legal challenges to regulatory interpretations and fewer appeals of reimbursable expenses specific to individual providers, which were common in the early years of the PRRB's operation. Early on, disputes over a provider's allowable costs in its cost report involving such expenses as owners' compensation, malpractice insurance, and marketing expenses were the norm, and generally these issues are simpler matters to adjudicate. With the evolution of Part A reimbursement to a prospective payment system, the issues on appeal with the PRRB frequently involve nuanced issues that implicate highly specialized and complex areas of law. Cases that have been adjudicated by the PRRB often reach the federal courts, and on occasion, are decided by the U.S. Supreme Court.[761] Permitting Board Members to serve more than two consecutive terms would allow them greater opportunity to follow the landscape of issues under judicial review, as it is not unusual for it to take years for cases to wind their way through the courts. Over their length of service, a Board Member develops an understanding of how certain issues are decided in the courts and applies that knowledge to the issues presented to the PRRB. The longer length of service would allow Board Members to obtain a deeper understanding of, and knowledge about, the issues and caselaw.

We also are considering a policy of permitting a Board Member to serve four consecutive 3-year terms, which would effectively permit an individual to serve as long as 12 years (with the potential of serving another 3 years, or 15 years total, if the Board Member would later be designated as Chairperson), as opposed to 9 years under this proposed regulatory change (with the potential of serving a total of 12 years by concluding their service on the PRRB as Chairperson). Making a Board Member eligible to serve as many four consecutive terms could have an advantage over three consecutive terms, which means even less turnover and a greater ability to retain highly qualified Board Members. We seek public comment on this alternative option of four consecutive terms rather than three.

We also are considering permitting a Board Member who ascends to the position of Chairperson to serve an additional two or three consecutive terms, instead of the proposed one additional consecutive term. Such a policy would permit an individual to serve 15 or 18 years (three 3-year terms as a Board Member and another two or three 3-year terms as Chairperson). Allowing a Board Member who is later designated as Chairperson to serve two or three additional consecutive terms would likely make all Board vacancies more attractive relative to current regulations (given the prospect of career progression and a longer tenure) and provide a longer period for a Board Member to gain experience prior to assuming the role of Chairperson, as they develop the knowledge, skills, and abilities in serve in a leadership capacity on the Board. Our intent in this proposal is to strike an appropriate balance between an appropriate level of turnover and CMS's desire to recruit and retain qualified Board Members. We solicit comment on these alternative options for the extended tenure of the Chairperson and whether our proposal or one of the alternative proposals best strikes this balance.

C. Maternity Care Request for Information (RFI)

1. Overview

As described in the White House Blueprint for Addressing the Maternal Health Crisis and in the CMS Maternity Care Action Plan we are committed to reducing maternal health disparities and improving maternal health outcomes during pregnancy, childbirth, and the postpartum period.[762] [763] In alignment with our commitment to addressing the maternal health crisis, this RFI seeks to gather information on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients as compared to non-Medicare patients. To the extent that the resources required differ between patient populations, we also wish to gather information on the extent to which non-Medicare payers, or other commercial insurers, may be using the IPPS as a basis for determining their payment rates for inpatient pregnancy and childbirth services and the effect, if any, that the use of the IPPS as a basis for determining payment by those payers may have on maternal health outcomes.

2. Use of Medicare Data for the Calculation of the IPPS MS–DRG Relative Weights

As explained in section II.A. of the preamble of this proposed rule, section 1886(d)(4) of the Act requires the Secretary to establish a classification of inpatient hospital discharges by diagnosis-related groups and a

[761] See *e.g.: Becerra* v. *Empire Health Found., for Valley Hosp. Med. Ctr.,* 142 S. Ct. 2354 (2022); *Sebelius* v. *Auburn Reg'l Med. Ctr.,* 568 U.S. 145 (2013); *Your Home Visiting Nurse Servs., Inc.* v. *Shalala,* 525 U.S. 449 (1999); and *Bethesda Hosp. Ass'n* v. *Bowen,* 485 U.S. 399 (1988).

[762] White House. White House Blueprint for Addressing the Maternal Health Crisis. 2022. Accessed January 2, 2024. *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.*

[763] CMS. CMS Cross Cutting Initiative: Maternity Care Action Plan. 2022. Accessed January 2, 2023. *https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.*

methodology for classifying specific hospital discharges within these groups. We refer to these groups of diagnoses as the IPPS Medicare Severity Diagnosis Related Groups (MS–DRGs). For each MS–DRG, the Secretary is required to assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. The Secretary is also required to adjust the MS–DRG classifications and weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58652), our goal is always to use the best available data overall for ratesetting, including the calculation of the IPPS MS–DRG relative weights. We primarily utilize Medicare claims data and Medicare cost report data for IPPS ratesetting for inpatient hospital services. The claims data we utilize is specific to the Medicare beneficiaries population, which includes people 65 and older or people with disabilities, End-Stage Renal Disease, or amyotrophic lateral sclerosis (ALS) that qualifies them for Medicare earlier than the age of 65.[764] Although most Medicare beneficiaries are 65 and older, in 2021 around 13% of the total share of Medicare beneficiaries were under the age of 65.[765] Therefore, people of reproductive age may have Medicare as their primary health insurance. Notably, a study from the National Institutes of Health found that pregnant women with disabilities have higher risks for maternal mortality and severe complications during birth and pregnancy compared to other pregnant women.[766] Thus, considering we utilize data that is specific to the Medicare beneficiary population in our ratesetting for inpatient hospital services we caution against using the IPPS rates and DRGs without first taking into account the characteristics of the Medicare beneficiary population.

3. Request for Information

This RFI seeks to gather information on differences between the resources required to provide inpatient obstetrical services to Medicare patients, on which the IPPS MS–DRGs relative weights for those services are based, as compared to non-Medicare patients. To the extent that the resources required differ, we also seek information regarding the extent to which non-Medicare payers, such as state Medicaid programs, may be using the IPPS MS–DRG relative weights to determine payment for inpatient obstetrical services and the effect, if any, that the use of those relative weights by those payers may have on maternal health outcomes. For instance, what types of modifications or assumptions, if any, are being made by payers when they are using the IPPS MS–DRG relative weights to account for the fact they are based on the Medicare beneficiary population? For example, one area where we are seeking additional information is the extent to which the use of the IPPS MS–DRG relative weights by state Medicaid programs may influence the number of low-risk cesarean deliveries for Medicaid patients. There are state Medicaid programs that have implemented payment initiatives, such as bundled payment models, blended payments, reduced payment or nonpayment for some procedures, and pay-for-performance models to improve maternal health outcomes. Some initiatives have demonstrated improved outcomes, such as a reduction in unnecessary cesarean deliveries.[767] Does the use of the IPPS MS–DRG relative weights as the basis for setting rates for other payers, to the extent it occurs, impact efforts to reduce low-risk cesarean deliveries? For example, if the differential between the hospital resources required for vaginal versus cesarean births is not the same for Medicare and non-Medicare patients, does the use of the IPPS MS–DRG relative weights for non-Medicare patients impact the number of low-risk cesarean deliveries? If so, how? For reference, IPPS MS–DRG relative weights and arithmetic length of stay for MS–DRGs for vaginal births and cesarean births are shown in Table X.C.–01.[768]

In summary, we pose the following questions to help facilitate feedback. We note that posing these questions to facilitate feedback in no way alters our longstanding principle, reiterated each year in the IPPS rulemaking, that facilities should not consider differences in relative weights when making treatment decisions.

- What policy options could help drive improvements in maternal health outcomes?
- How can CMS support hospitals in improving maternal health outcomes?
- What, if any, payment models have impacted maternal health outcomes, and how?
- What, if any, payment models have been effective in improving maternal health outcomes, especially in rural areas?
- What factors influence the number of vaginal deliveries and cesarean deliveries?
- To what extent do non-Medicare payers, such as state Medicaid programs, use the IPPS MS–DRG relative weights to determine payment for inpatient obstetrical services? What effect, if any, does the use of those relative weights by those payers have on maternal health outcomes?
- To what extent are Medicare claims and cost report data reflective of the differences in relative costs between vaginal births and cesarean section births for non-Medicare patients?
- Are there other data beyond claims and cost reports that Medicare should consider incorporating in development of relative weights for vaginal births and cesarean section births?
- What impact, if any, does the relatively lower numbers of births in Medicare have on the variability of the relative weights?
- What effect, if any, does potential variability in the relative weights on an annual basis have on maternal health outcomes?

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[764] Who's eligible for Medicare? U.S. Department of Health and Human Services. Accessed January 2, 2024. *https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html.*

[765] Medicare Beneficiaries at a Glance 2023 Edition. Centers for Medicare and Medicaid Services. *https://data.cms.gov/infographic/medicare-beneficiaries-at-a-glance.*

[766] Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. JAMA Netw Open. 2021;4(12):e2138414. Published 2021 Dec 1. doi:10.1001/jamanetworkopen.2021.38414.

[767] MACPAC. Medicaid Payment Initiatives to Improve Maternal and Birth Outcomes. MACPAC. Published April 2019. *https://www.macpac.gov/wp-content/uploads/2019/04/Medicaid-Payment-Initiatives-to-Improve-Maternal-and-Birth-Outcomes.pdf.*

[768] For other obstetrics MS–DRGs not listed in the table, refer to MS–DRG Definitions Manual: MDC 14 Pregnancy, childbirth and the puerperium located at: *https://www.cms.gov/icd10m/FY2024-nprmversion41.0-fullcode-cms/fullcode_cms/P0017.html.*

TABLE X.C.-01: IPPS MS-DRG RELATIVE WEIGHTS AND GEOMETRIC MEAN LENGTH OF STAY (LOS) FOR VAGINAL AND CESAREAN DELIVERIES (FY 2021 - FY 2025)

			Proposed FY 2025		FY 2024		FY 2023		FY 2022		FY 2021	
MS-DRG[1]	Delivery Type[2]	Annual Medicare Cases[3]	Weight	LOS	Weight	LOS	Weight	LOS	Weight	LOS	Weight	LOS
783	Cesarean Section with MCC	112	1.8421	4.6	1.7718	4.5	1.9297	4.7	1.8749	4.8	1.8727	4.8
796	Vaginal Birth with MCC	10	1.2766	2.9	1.4184	2.5	1.3130	3.6	1.0708	3.6	1.0679	3.6
784	Cesarean Section with CC	265	1.0735	3.1	1.0241	3.1	1.0440	3.1	1.0959	3.3	1.0949	3.3
797	Vaginal Birth with CC	40	0.9683	2.3	0.9959	2.4	0.9279	2.1	0.9194	2.4	0.9199	2.4
785	Cesarean Section without MCC/CC	202	0.8731	2.5	0.8663	2.5	0.9121	2.6	0.9168	2.7	0.9153	2.7
798	Vaginal Birth without MCC/CC	32	0.9683	2.3	0.8112	2.0	0.9279	2.1	0.8275	2.1	0.8273	2.1
786	Cesarean Section with MCC	398	1.5746	4.2	1.7495	4.3	1.6150	4.2	1.5944	4.3	1.5911	4.3
805	Vaginal Birth with MCC	312	0.9931	2.8	1.0082	2.8	1.0056	2.8	1.0299	2.9	1.0268	2.9
787	Cesarean Section with CC	981	1.0577	3.3	1.0511	3.3	1.0653	3.2	1.0644	3.5	1.0627	3.5
806	Vaginal Birth with CC	1153	0.7205	2.3	0.7467	2.3	0.6978	2.3	0.7346	2.3	0.7339	2.3
788	Cesarean Section without MCC/CC	700	0.9011	2.9	0.8550	2.7	0.8724	2.7	0.8874	3.0	0.8871	3.0
807	Vaginal Birth without MCC/CC	1534	0.6340	2.0	0.6543	2.0	0.6314	2.0	0.6423	2.1	0.6411	2.1

[1] MS-DRG definitions can be located in the ICD-10 MS-DRG Definitions Manual Files V41.1 located at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software

[2] CC refers to complications and comorbidities. MCC refers to major complications and comorbidities.

[3] For purposes of illustrating the approximate annual number of Medicare FFS cases in each MS-DRG, this column shows case counts based on the data used to develop the proposed FY 2025 MS-DRG relative weights, as discussed in section II.D. of the preamble of this proposed rule.

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D. Request for Information on Obstetrical Services Standards for Hospitals, CAHs, and REHs

1. Background

CMS establishes health and safety requirements for Medicare-certified providers and suppliers and selected Medicaid provider types. The requirements apply to all patients served by these facilities and must be met in order for facilities to participate in the Medicare and Medicaid programs. Conditions of participation (CoPs) for hospitals, CAHs, and rural emergency hospitals (REHs) set regulatory standards for many of the basic functions of such hospitals, as well as for some optional services that hospitals are not required by law to provide. Hospital CoPs at 42 CFR part 482 include standards regarding the responsibilities of the governing body, requirements for protecting patient rights, quality assessment and performance improvement requirements (QAPI), medical staff standards, and infection prevention and control and antibiotic stewardship requirements. All of these current standards together exist to protect patient health and safety, including the health and safety of pregnant, postpartum, and birthing patients. Similar provisions for CAHs and REHs are found at 42 CFR 485 subparts F and E, respectively.

Currently, there are no baseline care requirements for hospitals, CAHs, and REHs that are specific to maternal-child services (that is, labor and delivery, prenatal and post-partum care, and care for newborn infants, alternately referred to in this discussion as obstetrical services, obstetrics, maternal health, or maternity care). In addition to obstetrical units, care for pregnant and postpartum patients may also occur in other parts of facilities such as other inpatient wards, emergency departments, hospital-associated outpatient departments, as well as in facilities without obstetrical units and/or emergency services. Such care may occur before, during, or after delivery. Given the ongoing concerns about the delivery of maternity care in Medicare and Medicaid certified hospitals, CAHs, and REHs, CMS plans to propose baseline health and safety standards for obstetrical services in the calendar year (CY) 2025 Outpatient Prospective Payment System/Ambulatory Surgical Center (ASC) proposed rule.

Access to maternity care in the U.S. has continued to decline in recent years. Specifically, it is estimated that up to 6.9 million women have low to no access to maternity care.[769] From 2014 to 2018, 53 rural counties experienced closures of their hospital-based obstetrical (OB) services. This is in addition to the 1,045 counties that already did not have obstetric services in 2014.[770] Furthermore, 200 urban counties lost one or more obstetric units between 2019 and 2020.[771] The March of Dimes published a report which found that there were closures across 12 states from 2019 to 2020, in which 21 rural counties lost one or more hospital obstetric units.[772] In 2019, an estimated 58.7 percent of rural counties had no obstetricians, 81.7 percent had no advanced practice midwives, 86.3 percent had no midwives, and 56.9 percent had no family physicians who delivered babies, and nearly a third of rural counties (608, 30.8 percent) had none of these types of OB clinicians.[773] Explanations for these closures include shortages of obstetricians and family physicians, low volume of births, and low-income/poor payer-mix in these communities.[774] When these units close, women must travel long distances to a hospital that has obstetrical services. Specifically, in a survey of 133 hospital administrators, those in areas that lost access to inpatient obstetric services also reported limited access to many supports and services (such as midwifery and doula care) indirectly related to inpatient obstetric care that have strong evidence of improving maternal and infant health outcomes.[775] Factors that affect the availability of rural hospital-based obstetric care include labor costs, liability insurance costs, a high proportion of births to people who are uninsured or covered by Medicaid, and low payment rates for maternity care services.[776] Lack of access contributes to women in rural areas having a nine percent increased probability of maternal mortality or morbidity as compared to women in urban areas.[777] Poor maternal health access disproportionately affects non-Hispanic black women, American Indian and Alaska Native women (AI/AN), low-income women and women with disabilities. For example, in 2021, the maternal mortality rate for non-Hispanic Black women was 69.9 deaths per 100,000 live births, 2.6 times the rate for non-Hispanic White women. Rates for Black women were significantly higher than rates for White and Hispanic women. The increases from 2020 to 2021 for all race and Hispanic-origin groups were significant.[778] CMS considers it imperative to address disparities in care when discussing policy changes for improving maternal health care.

In Fall 2023, CMS launched the first-ever ''Birthing-Friendly'' designation icon on CMS's Care Compare online tool to describe facilities with high-quality maternity care. To earn the designation, hospitals and health systems report their progress on our Maternal Morbidity Structural Measure to the Hospital Inpatient Quality Reporting (IQR) Program. The measure identifies whether a hospital or health system has participated in a statewide or national perinatal quality improvement collaborative program and implemented evidence-based quality interventions in hospital settings to improve maternal health, such as maternal safety bundles. Maternal safety bundles have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and non-medically indicated Cesarean deliveries.[779] [780] [781] Hospitals and health professionals also have access to evidence-based best practices for determining the risk of obstetric

[769] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. *https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf.*

[770] Kozhimannil KB, Interrante JD, Tuttle MKS, Henning-Smith C. Changes in Hospital-Based Obstetric Services in Rural US Counties, 2014–2018. JAMA. 2020;324(2):197–199.

[771] American Hospital Association, 2019–2020.

[772] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. *https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf.*

[773] *https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2020/06/RHRC_PB168_Patterson.pdf.*

[774] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. *https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf* and American Hospital Association, 2019–2020.

[775] *https://rhrc.umn.edu/wp-content/uploads/2022/12/UMN_Infographic_Comparison-of-Evidence-based-supports.pdf*

[776] The Government Accountability Office, GAO–23–105515, MATERNAL HEALTH: Availability of Hospital-Based Obstetric Care in Rural Areas, *https://www.gao.gov/assets/gao-23-105515.pdf.*

[777] Hostetter M, Klein S. Restoring Access to Maternity Care in Rural America. The Commonwealth Fund. September 20, 2021. Available at: *https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-careruralamerica.* Accessed May 17, 2022.

[778] *https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm.*

[779] Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[780] Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. Am J Obstet Gynecol 2017;216(3):298.e1–298.e11.

[781] Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. Am J Obstet Gynecol 2018;218:S4.

hemorrhage and hypertension and for managing patients with these complications (including in the emergency setting). Yet, these best practices are not universally utilized nor incorporated into facilities' standards of care.[782] We direct readers to the quality, safety, and oversight memorandum (QSO–22–05-Hospitals) released by CMS,[783] which encourages hospitals to consider implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, to support the delivery of equitable, high-quality care for all pregnant and postpartum individuals. Facilities could implement these best practices voluntarily as part of a hospital's QAPI program (§ 482.21), which requires that hospitals develop, implement, and maintain an effective, ongoing, hospital wide, data-driven quality assessment and performance improvement program. The Quality Safety and Oversight (QSO) memo (QSO–22–05–Hospitals) further directs hospitals to a variety of resources available to assist in improvement efforts. These include the following:

- Agency for Healthcare Research and Quality Toolkit for Improving Perinatal Safety *https://www.ahrq.gov/patient-safety/settings/labor-delivery/perinatal-care/index.html*
- Centers for Disease Control and Prevention-Funded Perinatal Quality Collaboratives *https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm*
- HRSA-Funded AIM Program Patient Safety Bundles *https://saferbirth.org/*
- HRSA-Funded Rural Health Information Hub Rural Maternal Health Toolkit *https://www.ruralhealthinfo.org/toolkits/maternal-health*
- Institute for Healthcare Improvement Tools *https://www.ihi.org/resources/tools*
- National Institute for Children's Health Quality National Network of Perinatal Quality Collaboratives *https://nichq.org/project/national-network-perinatal-quality-collaboratives*
- The Joint Commission Provision of Care, Treatment, and Services Standards for Maternal Safety *https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/*
- U.S. Department of Health and Human Services and March of Dimes Public-Private Partnership, Maternal Health Collaborative to Advance Racial Equity (Maternal HealthCARE), Quality Improvement Initiative *https://www.maternalhealthcare.org/*

This list is not exhaustive. We recommend that hospitals also explore other national resources, as well as those specific to their state and region.

In the FY 2023 IPPS/LTCH PPS proposed rule, we published a maternal health RFI that solicited feedback on a wide range of maternal health issues and opportunities for CMS to improve maternal health care (87 FR 28549).[784] In response, some commenters were concerned that failure to comply with the new CoP would result in the loss of Medicare certification, that access to obstetrical care would be negatively impacted, that a new CoP may potentially exacerbate rates of maternal morbidity/mortality, and that a new maternal health CoP would exacerbate disparities in obstetrical care. Other commenters, including the American College of Obstetrics and Gynecology (ACOG) and the American Medical Association (AMA) supported the creation of a CoP specifically for labor and delivery, recognizing that CoPs establish minimum health and safety standards across participating entities and institutions, and recommending that CMS explore options to establish such CoPs for participating hospitals with relevant stakeholders.[785]

2. Obstetrical Services CoP

With this RFI, we hope to further explore such options and plan to propose a targeted obstetrical services CoP to establish baseline requirements for obstetrical care within participating facilities in the CY 2025 OPPS/ASC proposed rule based in part on public comments received in response to this RFI. The comments that we receive on this RFI will help to inform CMS on potential proposals that may be included in the proposed rule. Therefore, we are seeking public comment on potential solutions that could reduce the rates of maternal mortality and reduce disparities in maternal mortality and morbidity, which can be implemented through the hospital CoPs. We believe it is necessary to develop a standard by which obstetrics care delivery is performed in order to address well-documented concerns regarding maternal morbidity, mortality, and maternity care access in the United States. The goal would be to ensure that any policy change to obstetrical services improves maternal health care outcomes and addresses preventable disparities in care but does not exacerbate access to care issues. We recognize that section 1801 of the Act prohibits federal interference in the practice of medicine and therefore we are seeking comment on interventions that do not interfere in medical practice.

Specifically, we are soliciting comment on what should be the overarching requirement, scope, and structure for an obstetrical services CoP. What types of facilities and care settings should such a CoP apply to (that is, all hospitals, hospitals with/without OB units, hospitals with/without emergency services, CAHs, REHs, outpatient settings, which may include inpatient and outpatient prenatal, postpartum, emergency, and birthing care services)? CoP policy options could include (but are not limited to) the following. We welcome data, alternatives, benefits, and descriptions of possible unintended consequences on these potential options:

- Creating an optional services CoP specific to obstetrical services, similar to the current Optional Services CoPs for Surgical services (42 CFR 482.51), Anesthesia services (42 CFR 482.52), Outpatient services (42 CFR 482.54), or Emergency services (42 CFR 482.55). In this case, hospitals providing obstetrical services would be required to ensure that obstetrical services are well organized and provided in accordance with nationally recognized standards of care and evidence-based best practices. Such a requirement would be flexible enough to be tailored to hospitals of differing sizes and capabilities. The organization of OB services would be required to be appropriate to the scope of the services offered, and to integrate the OB services with other departments

[782] Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[783] *https://www.cms.gov/files/document/qso-22-05-hospitals.pdf.*

[784] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and NonQualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, May 10, 2022 (87 FR 28549). *https://www.govinfo.gov/content/pkg/FR-2022-05-10/pdf/2022-08268.pdf.*

[785] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, (August 10, 2022; (87 FR 49291)) *https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf.*

of the hospital, as appropriate. Policies governing obstetrical care would need to be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

- Modelling an OB services CoP after infection prevention and control stewardship program CoPs (42 CFR 482.42). This could include requirements relating to service organization and policies, leadership responsibilities, and application to multi-hospital systems.
- Requiring hospitals to develop standard processes for managing pregnant, birthing, and postpartum patients with or at risk for: (1) obstetric hemorrhage (a leading cause of maternal mortality); and (2) severe hypertension (a common pregnancy complication). Best practices for handling these issues, such as those highlighted in the resources cited above, already exist and CMS could require that hospitals establish policies that adopt or are consistent with existing accredited protocols.

Additionally, we solicit public comment on the following questions:

- What are existing acceptable standards of practice, organization, and staffing for obstetrical services (including staff qualifications and scope of practice considerations) in hospital obstetrical wards, emergency departments, CAHs, and REHs?
- What are existing regulatory barriers to quality care for pregnant and postpartum patients in hospital obstetrical wards, hospitals and CAHs that do not operate obstetrical wards, emergency departments, and in REHs?
- What regulatory changes are needed to ensure quality care for all pregnant, laboring, and postpartum patients across all care settings? Would establishing regulatory standards for organization, staffing, and for delivery of services for obstetrical units, similar to the existing standards for surgical services, advance this goal? What additional standards should be considered?
- How could CMS better understand patients' experience of maternity care? What tools or instruments exist to understand individuals' experience of maternity care? How might CMS incorporate these tools or instruments into an obstetrical CoP?
- How would an obstetrical services CoP impact access to care for pregnant, birthing, and postpartum individuals? How will the CoP impact hospitals with respect to factors that have led some facilities to close their maternity units, including high costs, labor shortages, and declining birth rates?
- What policy options would help alleviate any potential unintended consequences of an obstetrical services CoP and the impact on maternity care access and workforce? How should these policy options account for variation in hospital size, volume, and complexity of services? What other hospital-specific factors should be accounted for?
- How would the growth in the number of birth centers affect the impact of establishing an obstetrical services CoP? As of February 2022, 400 midwifery-led birth centers exist across 40 states and Washington DC, with their numbers more than doubling in the last decade (representing 0.52 percent of births in 2017).[786] Birth centers, which are not subject to the Emergency Medical Treatment and Labor Act (EMTALA),[787] treat primarily low risk pregnancies. However, in approximately 18 percent of cases birth centers will direct or transfer pregnant or postpartum individuals or newborns to a hospital.[788]
- What should minimum oversight requirements be for an obstetrical unit? We believe it is necessary to require that obstetrical units (including patient rooms/suites, operation rooms, and postpartum/recovery rooms whether combined or separate) be supervised by an experienced certified nurse practitioner, physician assistant, certified nurse midwife, or a doctor of medicine or osteopathy. Experienced oversight is necessary to ensure safe, high-quality care. However, we welcome comments on staffing and oversight requirements for obstetrical units, including whether these oversight requirements in an obstetric unit lead to improved quality outcomes for the mother and the baby or may result in unintended consequences. We also welcome comments on whether there should be similar or different oversight requirements for small hospitals, CAHs, and REHs.
- What should be required with respect to credentialling of health professionals to provide obstetrical services within a specific facility? We understand that health professionals (midwives, advanced practice providers, physicians, doulas, etc.) have differing skill sets and expertise. Therefore, we would expect that facility credentialling of health professionals to provide obstetrical services, consistent with state law, must be delineated for all practitioners providing obstetrical care in the facility in accordance with the competencies of each practitioner and that the facility maintain a roster of practitioners specifying the duties and privileges of each practitioner. Such a requirement would be consistent with the existing surgical services CoP (42 CFR 482.51(a)(4)).
- Should obstetrical units be required to maintain a minimum set of obstetrical care equipment and supplies? We recognize that facilities have different capacities and populations, and we are seeking comment on whether there is a core set of equipment and supplies that could enhance obstetrical readiness. For example, facilities might need to ensure that all delivery rooms have a call-system, fetal monitoring capabilities, adult and neonatal resuscitation equipment, accessible medical equipment, and adequate provisions for emergent/precipitous deliveries, obstetrical emergencies (such as hypertensive emergencies and hemorrhage), and immediate post-delivery care. Should hospitals and CAHs without obstetrical units, emergency departments, and REHs have similar requirements? Such requirements would be consistent with the existing surgical services CoP (42 CFR 482.51(b)(3)).
- Beyond what is already required for emergency department (ED) patients under EMTALA, should a hospital obstetrical services CoP include a requirement for transfer protocols for when a non-ED patient needs care that exceed the capability of the hospital (that is, inpatient to inpatient transfers)? Should a similar requirement apply to hospitals and CAHs without emergency services and/or obstetrical services?
- Are there additional ways the CoPs could improve or address the health and safety of pregnant and postpartum patients across all care settings?
- Are there refinements to Medicare and/or Medicaid payment structures for obstetrics care, and/or perinatal care that could improve the delivery of maternal care, and also address existing disparities? We are interested in specific refinements that are within CMS statutory authorities.

3. Staff Training

According to the AHA, between 2015 and 2019, there were at least 89 obstetric unit closures in the U.S.,[789]

[786] MacDorman MF, Declercq E. Trends and state variations in out-of-hospital births in the United States, 2004–2017. Birth. 2019 Jun;46(2):279–288. doi: 10.1111/birt.12411. Epub 2018 Dec 10. PMID: 30537156; PMCID: PMC6642827.

[787] *https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/emtala.pdf.*

[788] *https://www.birthcenters.org/news/nbcs2.*

[789] American Hospital Association Infographic *https://www.aha.org/system/files/media/file/2022/04/Infographic-rural-health-obstetrics-15ap22.pdf* accessed 12/06/2023.

with a disproportionate impact on rural and underserved communities.[790] [791] [792] [793] Given the increasing number of areas across the country with limited to no access to maternal health care, emergency departments, CAHs, and REH and non-obstetrical professionals working in these settings may experience a higher acuity and frequency of patients needing obstetrical care. Moreover, a number of emergency departments, CAHs, and REHs, especially in rural areas, may be staffed by clinicians with less training in obstetrical emergencies.[794] [795] [796] [797] [798] Rural hospitals with and without obstetric units report that their greatest concerns in responding to local obstetric emergencies include a lack of specialty care providers and a lack of skills to address emergency births.

We note that existing hospital CoPs for emergency services (42 CFR 482.55) already require that ''there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.'' In addition, EMTALA requires Medicare-participating hospitals, CAHs, and REHs with emergency departments to ''provide a medical screening examination (MSE) [. . .] for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. Applicable facilities are then required to provide stabilizing treatment for patients with EMCs.'' [799] Furthermore, existing the Joint Commission (TJC) standards on the provision of care, treatment, and services standards for maternal safety require the education of all staff and providers who treat pregnant/postpartum patients on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.[800] The standards also recommend that hospitals use in-situ training and drills that include multidisciplinary teams. We expect that facilities will ensure their emergency staff are trained to handle obstetrical related emergencies in compliance with CMS' CoPs, EMTALA, and TJC standards.

Despite these existing regulations and standards, several organizations have cited that obstetrical readiness for hospitals with and without obstetrical services is suboptimal.[801] [802] [803] In these situations, appropriate training, best practice protocols (such as recognizing early warning signs of hemorrhage and other adverse events associated with pregnancy and birth), and transfer protocols are critical to averting avoidable maternal complications and deaths, establishing and maintaining facilities' obstetrical readiness,[804] and ensuring compliance with existing CoP and EMTALA regulations.

We are interested in feedback on requiring additional training, protocols, or equipment for hospital non-OB unit, emergency department, CAH, and REH staff that treat pregnant and postpartum patients as a stop-gap measure to ensure individuals living without access to maternal health care can safely and effectively receive necessary services. Training requirements could encompass training in common obstetrical conditions and emergencies or training on methods for improving the respectful delivery of care to pregnant and postpartum patients or both. This could be connected to the hospital emergency services CoPs or applied more broadly to all or a subset of hospital, CAH, and REH staff and require that such facilities demonstrate that staff have adequate or minimum obstetrical training as well as training in hospital protocols, such as transfer protocols for when a pregnant, birthing, or postpartum persons under the facilities' care (including emergency department patients) need a higher level of obstetrical care than the hospital is able to provide. We also seek feedback on how potential challenges with such a requirement could be mitigated.

We note that since hospitals are neither required to provide obstetrical services nor emergency services, we are interested in ways to mitigate potential impacts and costs to hospitals in implementing such a possible requirement. We seek feedback from the public to learn more about the impact of this particular potential requirement and evidence supporting the need for such a requirement.

Therefore, we are seeking public comment specifically on the following:

- Should minimum OB staff training requirements (both initial and ongoing) be included in an obstetric services CoP? The Joint Commission (TJC) requires the education of all staff and providers who treat pregnant/postpartum/birthing patients on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.[805] Should a similar requirement be included in an OB services CoP? Are there other requirements for training that should be included, such as neonatal resuscitation?
- Given the rate of OB unit closures, should CMS require a minimum obstetrical training standard for hospital/CAH non-OB unit, emergency department, REH, or other non-OB staff that may care for pregnant, birthing, and postpartum patients to improve maternal health outcomes? What evidence exists to support the need for further or baseline obstetrical training for these non-obstetrical health professionals? What might this training entail? Which clinical staff and which facility types should such requirements apply to? What intervals should such training be required? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-based trainings, best practice standards, and protocols are currently available? What are the barriers to accessing such obstetrical training, including in rural areas? What are policy options to mitigate any potential unintended consequences or provider burden of such a requirement? Should this training apply to all hospitals or a subset (that is, those with emergency services; or those with emergency services but no obstetrical services)? For example, the existing Emergency Services CoP at 42 CFR 482.55 could be revised to require that hospitals with emergency services (which would include hospitals with and without obstetrical services units) establish best

[790] *https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf.*

[791] *https://jamanetwork.com/journals/jama/fullarticle/2674780.*

[792] *https://pubmed.ncbi.nlm.nih.gov/32473598/.*

[793] *https://jamanetwork.com/journals/jama/fullarticle/2674780.*

[794] *https://ilpqc.org/ILPQC%202020+/HTN/OB%20triage%20Wolf%20Delao%20Baker%20and%20Zavotsky%202021.pdf.*

[795] *https://www.cdc.gov/wcms/video/low-res/hearher/2022/819819Role-EmergMed-Specialists.mp4.*

[796] *https://www.awhonn.org/wp-content/uploads/2020/11/ENA-AWHONN-Consensus-Statement-Final-11.18.2020.pdf.*

[797] *https://kffhealthnews.org/news/article/doctors-are-disappearing-from-emergency-rooms-as-hospitals-look-to-cut-costs/.*

[798] *https://www.annemergmed.com/article/S0196-0644(18)30267-1/fulltext.*

[799] *https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act.*

[800] *https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/.*

[801] *https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality.*

[802] *https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf.*

[803] *https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf.*

[804] *https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/.*

[805] *https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/.*

practice protocols, transfer protocols, and regular staff training for management of common obstetrical conditions and emergencies.

- Should such additional staff training include separate training on methods for providing respectful care for pregnant, birthing, and postpartum patients in an effort to improve maternal health outcomes? Which staff should this apply to? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-based trainings on respectful care for pregnant, birthing, and postpartum patients are currently available?
- Should staff also be trained on implicit bias, trauma-informed care, or other specific training topics aimed at addressing bias and reducing disparities in maternity care? Which staff should this apply to? Is there data and evidence that demonstrates that implicit bias and trauma-informed care training improves maternal health care outcomes? If so, what evidenced-based trainings are currently available?
- Should additional staff training include separate training on the screening, assessment, treatment, and referral for maternal depression and related behavioral health disorders by staff? Which staff should this apply to? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-based trainings are currently available?
- For all possible training topics discussed in above bullets of this section, what is the recommended frequency of staff training needed to balance maintaining skills and teamwork with minimizing associated burdens (*i.e.,* staff time, costs), especially for rural facilities?
- What additional policies should CMS consider to support the obstetrical readiness of hospitals with and without labor and delivery units for obstetrical emergencies, high-risk pregnancy related conditions, and common obstetrical conditions?

4. Data

We are also interested in understanding if and how requiring hospitals to submit data related to maternal morbidity and mortality could be incorporated into any maternal services CoP. In January 2010, the Transforming Maternity Care Symposium Steering Committee issued a Blueprint for Action that included improving the availability and ease of collection of standardized maternity care data in order to encourage high quality clinical care, allow performance measurement and comparison, and support creation and implementation of a national public reporting system for maternity care data available to all relevant stakeholders in order to drive improvements in maternity care.[806] Maternal health advocates have stated that the lack of maternal morbidity and mortality data limits where meaningful changes can occur. Currently, Maternal Mortality Review Committee (MMRC) data reporting is dependent upon state requirements and often voluntary reporting by health care facilities. While there are concerns about a lack of data, some parties have suggested that, though voluntary, MMRC data collection from facilities is robust and timely. We encourage facilities to report data to their state MMRC, where they exist and in alignment with requirements in their specific states. However, not all states have an MMRC. We believe that improving the available data would enable facilities to compare data and conduct more complete assessments of their maternal health readiness and opportunities for growth and improvement. To that end, we are interested in public comment on the following:

- How could CMS help improve data collection related to maternal morbidity and mortality across all demographics?
- Should hospitals be required to directly report to MMRCs when available? (*https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html#maternal-mortality-review*)
- Could such a data collection requirement be incorporated into an obstetrical services CoP, or would it be more appropriately incorporated into another existing hospital CoP, such as QAPI?
- Are there common critical data elements that would be most important and appropriate to collect through a CoP aimed at improving maternal health data? Are there data standards currently available or under development that can support standardized reporting? How do we ensure data collection encompasses all demographics?
- How can any associated burden of possible future data collection and reporting requirements for providers be mitigated?

D. Proposed Changes to the Payment Error Rate Measurement (PERM)

The Payment Integrity Information Act of 2019 requires federal agencies to annually review programs susceptible to significant improper payments, estimate the amount of improper payments, report those estimates to Congress, and submit a report on actions the agency is taking to reduce the improper payments.

Medicaid and the Children's Health Insurance Program (CHIP) were identified as programs at risk for significant improper payments. We measure Medicaid and CHIP improper payments through the Payment Error Rate Measurement (PERM) program. Under PERM, reviews are conducted in three component areas (FFS, managed care, and eligibility) for both the Medicaid program and CHIP. The results of these reviews are used to produce national program improper payment rates, as well as state-specific program improper payment rates. The PERM program uses a 17-state, 3-year rotation cycle for measuring improper payments, so every state is measured once every 3 years.

Section 202 of Division N of the Further Consolidated Appropriations Act, 2020 (FCAA, 2020) (Pub. L. 116–94) amended Medicaid program integrity requirements in Puerto Rico. Puerto Rico was required to publish a plan, developed by Puerto Rico in coordination with CMS, and approved by the CMS Administrator, not later than 18 months after the FCAA's enactment, for how Puerto Rico would develop measures to comply with the PERM requirements of 42 CFR part 431, subpart Q. Puerto Rico published this plan on June 20, 2021,[807] and it was approved by the CMS Administrator on June 22, 2021. We propose to remove the exclusion of Puerto Rico from the PERM program found at 42 CFR 431.954(b)(3). In compliance with section 202 of Division N of the FCAA, 2020, Puerto Rico has developed measures to comply with the PERM requirements of 42 CFR part 431, subpart Q. Including Puerto Rico in the PERM program will increase transparency in its Medicaid and CHIP operations and will improve program integrity efforts, that protect taxpayer dollars from improper payments.

Puerto Rico would be incorporated into the PERM program starting in RY27 (Cycle 3), which covers the payment period between July 1, 2025 through June 30, 2026.

[806] Angood P. B, Armstrong E. M., Ashton D, Burstin H., Corry M. P, Delbanco S. F, et al. Blueprint for action: Steps toward a high-quality, high-value maternity care system. Women's Health Issues. 2010;20(1) (Suppl. 1): S18–S49.

[807] *https://www.medicaid.pr.gov/pdf/Congress/PRDOH_Congressional%20Report%202%20PERM%20Compliance%20Plan_FINAL[2][1].pdf.*

F. CoP Requirements for Hospitals and CAHs To Report Acute Respiratory Illnesses

1. Background

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. Hospitals (all hospitals to which the requirements of 42 CFR part 482 apply, including short-term acute care hospitals, LTC hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services under 42 CFR part 485, subpart F, must be certified as meeting Federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements set out the patient health and safety protections established by the Secretary for various types of providers and suppliers. The specific statutory authority for hospital CoPs is set forth in section 1861(e) of the Act; section 1820(e) of the Act provides similar authority for CAHs. The hospital provision at section 1861(e)(9) of the Act authorizes the Secretary to issue any regulations he or she deems necessary to protect the health and safety of patients receiving services in those facilities; the CAH provision at section 1820(e)(3) of the Act authorizes the Secretary to issue such other criteria as he or she may require. The CoPs are codified at 42 CFR part 482 for hospitals, and at 42 CFR part 485, subpart F, for CAHs.

Our CoPs at § 482.42 for hospitals and § 485.640 for CAHs require that hospitals and CAHs, respectively, have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases and for the optimization of antibiotic use through stewardship. Additionally, the programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the required hospital and CAH programs must also be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs.

Infection prevention and control is a primary goal and responsibility of hospitals and CAHs in their normal day-to-day operations, and these programs have been at the center of initiatives taking place in hospitals and CAHs since the beginning of the Public Health Emergency (PHE) for COVID–19. Our regulations for hospitals and CAHs at §§ 482.42(a)(3) and 485.640(a)(3), respectively, require infection prevention and control program policies to address any infection control issues identified by public health authorities.

On March 4, 2020, we issued guidance stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other health care facility staff as appropriate about the presence of a person under investigation for COVID–19 (QSO–20–13-Hospitals). CMS followed this guidance with an interim final rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' published on September 2, 2020 (85 FR 54820), that required hospitals and CAHs to report important data critical to support the fight against COVID–19. The IFC provisions specifically required that hospitals and CAHs report specified information about COVID–19 in a format and frequency specified by the Secretary. Examples of data elements that could be required to be reported included things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. These elements proved essential for developing and directing implementation of infection prevention and control guidance, as well as resource allocations and technical assistance during the PHE.

On August 10, 2022, we finalized revisions to the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs (at §§ 482.42(e) and (f); and 485.640(d) and (e), respectively) in the FY 2023 IPPS final rule ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates'' (87 FR 48780, 49409), to require that, beginning at the conclusion of the COVID–19 PHE declaration and continuing until April 30, 2024, hospitals and CAHs must electronically report information about COVID–19 and seasonal influenza virus, influenza-like illness, and severe acute respiratory infection in a standardized format specified by the Secretary. In establishing these requirements, we stressed that such reporting continued to be necessary for CMS to monitor whether individual hospitals and CAHs were appropriately tracking, planning for, responding to, and mitigating the spread and impact of COVID–19 and influenza on patients, the staff who care for them, and the general public (87 FR 49377). We also noted that the approach finalized in that rule would provide a path towards ending the overall reporting of COVID–19-related data between the end of the current PHE and April 2024, when those requirements would sunset (87 FR 49379).

2. Hospital Respiratory Illness Data Are and Will Continue To Be Critical for Patient Health and Safety

The COVID–19 pandemic highlighted the importance of taking a broad view of patient safety—one that recognizes patient safety is determined not just by what is happening at the bedside, but also what is happening in the broader hospital, and in hospitals across the region, state, and country. At the same time, it also demonstrated the patient benefits of strong integration between public health and health care systems, particularly when data are available to direct collaborative actions that protect patient and public health and safety. Data from health care providers remain the key driver to identify and respond to public health threats, yet health care and public health data systems have long persisted on separate, often poorly compatible tracks.

Hospital and CAH-reported data on COVID–19, influenza, and RSV infections among patients, as well as hospital bed capacity and occupancy rates, continue to play a critical role in infection prevention and control efforts at every level of the health system. The value of these data extend beyond the COVID–19 PHE. For example, source control remains an important intervention during periods of higher respiratory virus transmission.[808] Data on hospital admissions reported under the current CoPs continue to inform national, state, and county recommendations for community and health care mitigation measures.[809]

[808] *https://www.cdc.gov/infectioncontrol/guidelines/core-practices/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fhicpac%2Frecommendations%2Fcore-practices.html.*

[809] Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) | CDC; 2023.12.14—IDPH Recommends Healthcare

Continued

Notably, the CDC recommends that health care facilities consider levels of respiratory virus transmission in the whole community when making decisions about source control. Comprehensive and consistent surveillance across hospitals creates a shared resource that all health care facilities in a community can use to inform infection control policies. Hospitals and CAH requirement to report this data ends in April 2024. Not maintaining this reporting would result in an absence of vital information on local, regional, and national transmission and impact of respiratory illness, with significant implications for both patient care and public health mitigation.

The data produced by hospital respiratory virus reporting requirements under the PHE informed coordination of hospital operations and were especially important to anticipate and prepare for surge conditions. Collaborative, data driven approaches can help to manage patient transfers and alleviate strained hospitals, ultimately aiding to improve patient care. Medical operations coordination centers (MOCCs) and similar structures showed promise as effective tools for facilitating medical surge response.[810] MOCCs are often rapidly stood up as needed and reliant on shared visibility across multiple, often competitive, hospitals. Standardized data collections enable MOCCs and other partners to support patient placements and transfers and identify patient load balancing needs.[811] This helps the health care community to prepare for and effectively respond to respiratory illness surges in ways that maintain the safety and availability of critical care services. MOCCs or similar structures were implemented in multiple jurisdictions to help place patients and mitigate strain.[812] Even without formal MOCCs, jurisdictions, health care coalitions, and health systems have used hospital capacity data to coordinate patient placement and reduce ED boarding and overcrowding.[813] These efforts are especially critical as surge conditions can impact quality of care and patient outcomes—many COVID–19 deaths were potentially attributable to surge-strained hospitals.[814] The data reported under the COP were important to inform MOCC operations and identify and mitigate strain on health care systems.

Insight into hospital and CAH capacity helps ensure capabilities are available to meet patient needs with quality care through enhanced planning, technical assistance, resource allocation, and coordination.[815] While health care entities often work independently within their own systems, health care partners are ultimately part of an ecosystem caring for patients in their community. This interdependency is especially highlighted during times of strain—whether it is due to temporary conditions such as diversion, permanent changes with facility closures, or PHEs. Regardless of facility status, the need for patient care remains—resulting in increased strain on surrounding hospitals. Health care coalitions (HCCs) are one example of local health care partners working together to increase local and regional health care resilience during respiratory illness surges and more.[816] HCCs plan and respond together, sharing real-time information and providing technical assistance to support their partners.[817] At the state level, in addition to patient placements and load balancing operations, hospital associations and state health departments have used hospital data to monitor for potential trends and to inform their response. Hospital capacity data helped to inform and monitor triggers for patient load balancing, allocations of scarce resources, and requests for additional resources or mutual aid.[818] Hospitals and health care systems can also use the information for planning purposes, identifying how their facility may be impacted and to help prepare accordingly.[819] Information sharing across the health care ecosystem helps the health care community to prepare for, and effectively respond to, respiratory illness surges in ways that maintain the safety and availability of critical care services.

Data from hospitals play a central role in guiding actions to reduce the prevalence of respiratory infections in the community.[820] In recognition of this point, the Biden-Harris Administration's National Biodefense Strategy includes a goal to, ''maintain and enhance an enduring domestic all-hazards hospital data collection capability, including data reporting and management systems, governance processes, and user guidance, to enable comprehensive data reporting for biosurveillance, situational awareness, and emergency response operations at the federal and STLT levels.'' [821]

The prevalence of respiratory infections in the community affects patient safety within hospitals in at least two ways: First, community prevalence is a key risk factor for within-facility pathogen transmission. Higher infection

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Facilities Adopt Mitigation Measures as Respiratory Viruses Increase (*illinois.gov*) 2024-doh-masking-advisory.pdf (*ny.gov*); Health Alert Network (HAN)—00503 | Urgent Need to Increase Immunization Coverage for Influenza, COVID–19, and RSV and Use of Authorized/Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023–2024 Winter Season (*cdc.gov*).

[810] Hick, J. L., Hanfling, D., & Wynia, M. (2022). Hospital Planning for Contingency and Crisis Conditions: Crisis Standards of Care Lessons from COVID–19. *Joint Commission journal on quality and patient safety, 48*(6–7), 354–361. *https://doi.org/10.1016/j.jcjq.2022.02.003.*

US Department of Health and Human Services. 2nd ed. Medical Operations Coordination Cells Toolkit; Nov 2021. Office of the Assistant Secretary for Preparedness and Response; Technical Resources, Assistance Center, and Information Exchange. *https://files.asprtracie.hhs.gov/documents/fema-mocc-toolkit.pdf.* Accessed Jan 30, 2024.

Valin JP, et. al. Physician executives guide a successful COVID–19 response in Colorado. NEJM Catalyst. Epub 2021 Oct 15. Accessed Jan 30, 2024. *https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0402.*

Villarroel L. Collaboration on the Arizona surge line: how COVID–19 became the impetus for private, public, and federal hospitals to function as one system. *NEJM Catalyst. Epub.* 2021 Jan.

[811] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/WA-HospitalSurge-March2020.aspx* (March 2020).

[812] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/CO-Combined-Hospital-Transfer-Cntr.aspx.*

[813] *e.g.,* Alaska Hospital Capacity Dashboard (arcgis.com); *https://files.asprtracie.hhs.gov/documents/aspr-tracie-hcc-engagement-in-covid-19-assessment.pdf.*

[814] Kadri SS, Sun J, Lawandi A, et al. Association between caseload surge and COVID–19 survival in 558 U.S. hospitals, March to August 2020. *Ann Intern Med.* Jul 06 2021.174(9):1240–1251.

Auld SC, Caridi-Scheible M, Blum JM, et al. ICU and ventilator mortality among critically ill adults with coronavirus disease 2019. *Crit Care Med.* 09 2020;48(9):e799-e804.

Keene AB, Admon AJ, Brenner SK, Gupta S, Lazarous D, Leaf DE, Gershengorn HB; STOP–COVID Investigators. Association of Surge Conditions with Mortality Among Critically Ill Patients with COVID–19. J Intensive Care Med. 2022 Apr;37(4):500–509. doi: 10.1177/08850666211067509. Epub 2021 Dec 23. PMID: 34939474; PMCID: PMC8926920.

[815] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Kentucky-Collaborates-Community.aspx.*

[816] *https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf.*

[817] *https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf.*

[818] Mitchell SH, Rigler J, Baum K. Regional Transfer Coordination and Hospital Load Balancing During COVID–19 Surges. *JAMA Health Forum.* 2022;3(2):e215048. doi:10.1001/jamahealthforum.2021.5048. *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/HCC-Regional-Approach-Illinois.aspx.*

[819] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Maryland-HCC-covid19.aspx.*

[820] COVID–19 Surveillance After Expiration of the Public Health Emergency Declaration—United States, May 11, 2023 | MMWR (*cdc.gov*).

[821] *National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf* (*whitehouse.gov*).

prevalence in the community unavoidably translates to higher prevalence among staff, patients, and visitors entering a facility. The more times a pathogen is introduced into a facility, the more times it has a chance to spread onward within that facility. Within-facility infection control measures can substantially mitigate this risk, but no single action confers absolute protection—rather, layered mitigation measures, particularly when those include community level actions, are most effective. Second, the community prevalence of respiratory infections is a key driver of health care worker absenteeism, which can lead to staff shortages that adversely affect patient safety.

Data on hospitalizations feature prominently on CDC's website and are directly tied to specific disease-prevention guidance (for example, whether mask-wearing is recommended in public indoor spaces). Additionally, analyses that measure the trajectory of waves of COVID–19 and seasonal influenza and analyses that generate forecasts have relied on nationally comprehensive data on hospital admissions.[822] Similarly, scenario models that have been used to generate seasonal projections for COVID–19 and that have informed vaccination policy are based on hospital admissions data.[823] The incidence of COVID–19 and influenza hospital admissions inform urgent messages from CDC on actions health care providers can take to protect their patients from respiratory viruses.[824] No other data source available to CDC has the same level of timeliness, geographic resolution and coverage, and interpretability as nationally comprehensive hospitalization surveillance.

Respiratory illness reporting proved invaluable during the COVID–19 PHE, and these data have significant and ongoing value for protecting patient health and safety. While the COVID–19 PHE has ended, SARS–CoV–2 continues to circulate throughout the globe. Although COVID–19 activity and hospitalization rates have been lower, than those of 2020 through early 2022, there was no epidemiologic bright line associated with the end of the PHE. For example, in January 2024, COVID–19 hospital admissions were only modestly lower than they were at the July 2022 or December 2022 peaks.[825] At the same time, other respiratory viruses have seen a resurgence, and the moderate COVID–19 burden coinciding with resurgent influenza and RSV has led to an overall hospitalization burden larger than observed during severe influenza and RSV seasons prior to the COVID–19 pandemic, placing patient health and safety at risk.[826]

The result of this ''new normal'' will be more burdensome respiratory virus seasons for the foreseeable future, which promises to place continued strain on the nation's hospitals.[827] In response to this changed landscape, public health agencies such as CDC have shifted prevention and control strategies from a focus on specific viruses to an approach that addresses the threats presented by the broader respiratory virus season, including overall impacts on hospital capacity and patient health and safety.[828]

The elevated risks of respiratory viruses in the post-PHE era present ongoing threats, both direct and indirect, to patient health and safety. As discussed elsewhere in this proposed rule, the COVID–19 PHE strained the health care system substantially, introducing new safety risks and negatively impacting patient safety in the normal delivery of care. Data from the pandemic showed that the incidence of health care associated infections would increase when COVID–19 hospitalizations were high,[829] creating a feedback loop between increased stress on hospitals, increased illness in the community, and negative effects on patient health and safety. Degradation in other measures of patient safety, including pressure ulcers and falls, further demonstrate how the strains associated with surge response adversely affect routine safety practices.[830] Elevated respiratory virus activity also impacts patient access to hospital care and services and the resiliency of the health care system overall. During the most severe waves of respiratory illness, hospitals see delays in elective procedures, bed capacity issues that require diversion, and other disruptions to routine patient care.[831]

3. Proposal To Continue Respiratory Illness Reporting in a Modified Form

In light of continued utility of respiratory illness data, we propose to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to extend a modified form of the current COVID–19 and influenza reporting requirements that will include data for RSV and reduce the frequency of reporting for hospitals and CAHs. These proposed requirements would take effect on October 1, 2024. While hospitals and CAHs are encouraged to voluntarily continue reporting these data in the interim, we recognize that there would be a 5-month gap between the sunset date for current reporting requirements (April 30, 2024) and the proposed implementation date for these new requirements. We welcome public comment on strategies to mitigate challenges and support an informed transition.

Specifically, we propose to replace the COVID–19 and Seasonal Influenza reporting standards for hospitals and CAHs at § 482.42(e) and (f) and § 485.640(d) and (e), respectively, with a new standard addressing respiratory illnesses to require that, beginning on October 1, 2024, hospitals and CAHs electronically report information about COVID–19, influenza, and RSV in a standardized format and frequency specified by the Secretary. To the extent determined by the Secretary, *we propose that* the data elements for which reporting would be required at this time include—

- Confirmed infections of respiratory illnesses, including COVID–19, influenza, and RSV, among hospitalized patients;
- Hospital bed census and capacity (both overall and by hospital setting and population group [adult or pediatric]); and

[822] CFA and NCIRD Modeling and Forecasting of Respiratory Diseases (*cdc.gov*).

[823] Public health impact of the U.S. Scenario Modeling Hub—ScienceDirect.

[824] Health Alert Network (HAN)—00503 | Urgent Need to Increase Immunization Coverage for Influenza, COVID–19, and RSV and Use of Authorized/Approved Therapeutics in the Setting of Increased Respiratory Disease Activity During the 2023–2024 Winter Season (*cdc.gov*).

[825] *https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00.*

[826] Respiratory Disease Season Outlook (*cdc.gov*).

[827] Respiratory Disease Season Outlook (*cdc.gov*).

[828] See *https://www.cdc.gov/respiratory-viruses/index.html* and data summaries of respiratory virus burden at *https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html. https://www.cdc.gov/respiratory-viruses/whats-new/track-hospital-capacity.html.*

[829] Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID–19) pandemic | Infection Control & Hospital Epidemiology | Cambridge Core; *https://www.nejm.org/doi/full/10.1056/NEJMp2118285*; The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network—PubMed (*nih.gov*); Impact of COVID–19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network—PubMed (*nih.gov*).

[830] *https://www.nejm.org/doi/full/10.1056/NEJMp2118285.*

[831] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9526134/*; Infect Control Hosp Epidemiol. 2022 Oct;43(10):1473–1476.doi: 10.1017/ice.2021.280. Epub 2021 Jun 24.; Changes in the number of intensive care unit beds in US hospitals during the early months of the coronavirus disease 2019 (COVID–19) pandemic—PubMed (*nih.gov*).

• Limited patient demographic information, including age.

We considered the data elements that proved most actionable and informative over the course of the COVID–19 PHE with evidence of protecting health and safety, as well as more recent lessons that have emerged during the 2023–2024 respiratory virus response.[832] We also considered ways to balance the burden of reporting on hospitals and CAHs with the need to maintain a level of situational awareness that will benefit hospitals and the patients and communities they serve. Therefore, outside a declared national PHE for an acute respiratory illness (as discussed further below), we propose that hospitals and CAHs would have to report these data on a weekly basis (either in the form of weekly totals or snapshots of key indicators) through a CDC-owned or supported system.

Sustained data collection and reporting outside of emergencies would help ensure that hospitals and CAHs maintain a functional reporting capacity that can be mobilized quickly when a new threat emerges to inform and direct response efforts (for example, resource allocations or patient load balancing within and across facilities) that protect patients and their communities. It will also provide the baseline data necessary to forecast, detect, quantify and, ultimately, direct responses to signals of strain. For example, to estimate the extent to which a novel SARS-CoV–2 variant threatens hospital capacity, analysts need data on a population's epidemiologic history (for example, the presence and magnitude of prior waves of SARS-CoV–2) and they need data to infer the relationship between respiratory virus admissions and strain on hospital capacity.

Unlike the previous and sunsetting hospital and CAH reporting CoPs, the reporting requirements proposed in this rule are not tied to a specific PHE declaration. PHE declarations are valuable tools to marshal nimble and fast emergency responses. However, there are many respiratory disease threats to hospital operations and patient safety that would not necessarily be subject to a PHE declaration nor have significant potential to become a PHE. In those instances, routine data about influenza hospitalizations and admissions are critical to inform allocation of resources to hospitals and planning to prevent disruptions to patient care.

These proposals are scaled back and tailored from the current post-COVID–19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would benefit patients and hospitals across the country while reducing reporting burden on hospitals and CAHs.

We welcome public comments on our proposals, and on ways that reporting burden can be minimized while still providing adequate data. We also welcome feedback on any challenges of collecting and reporting these data; ways that CMS could reduce reporting burden for facilities; and alternative reporting mechanisms or quality reporting programs through which CMS could instead effectively and sustainably incentivize reporting. Finally, we welcome comments on the value of these data in protecting the health and safety of individuals receiving treatment and working in hospitals and CAHs.

4. Soliciting Input on Collecting Data by Race and Ethnicity

The COVID–19 pandemic devastated communities across the United States, and socially vulnerable populations have been disproportionately affected. From the beginning, reports indicated that people of color and people from economically disadvantaged communities were at an increased risk of becoming sick from COVID–19, being hospitalized due to COVID–19, and dying from COVID–19, compared to members of predominantly white and/or affluent communities.[833] At the same time, the data necessary to detect and respond to these disparities were not consistently available from core data sources, including hospitalization data reported by hospitals and CAHs under §§ 482.42(e) and (f); and 485.640(d) and (e), respectively.

We are committed to protecting patients from all communities and preventing inequities caused or exacerbated by respiratory viruses like COVID–19, influenza, and RSV. Timely, complete data on racial and ethnic differences in hospitalizations are critical to meeting that commitment in policy solutions. In addition, timely, complete data on granular demographic information can assist us in assuring the health and safety of individuals receiving health care services to the greatest extent possible. For that reason, we seek comment on expanding the scope of demographic information collection to further support improvements in clinical outcomes while also protecting privacy and the safety of demographic groups.

At the same time, we recognize that efforts to improve the collection of race/ethnicity data and standards for how these data are captured are still evolving.[834] We also recognize that in the context of aggregate data collection, requesting multiple demographic details for each data element may increase data collection and reporting burdens.

For this reason, we invite comment as to whether race/ethnicity demographic information should be explicitly included as part of requirements for ongoing reporting beginning on October 1, 2024. We are particularly interested in comments that address the ways these additional data elements could be used to better protect patient and community health and safety both during and outside of a declared PHE. We are interested in comments on how to protect patient privacy within demographic groups and best use the data to inform public health efforts without stigmatizing demographic groups.[835] We are also interested in comments that address system readiness and capacity to collect and report these data. Finally, we request comments as to whether the additional demographic factors including socioeconomic or disability status that may be associated with disparities in outcome, should be required for mandatory ongoing reporting starting on October 1, 2024. After considering the public comments on this issue, we may decide to finalize a policy of collecting demographic information on race/ethnicity and/or additional factors.

5. Proposal To Collect Additional Elements During a PHE

Routinely collected data from hospitals also power forecasts that inform decision making during an emergency response.[836] In the face of future illness emergencies, we anticipate stakeholders—including health care systems—will continue to

[832] *https://emergency.cdc.gov/han/2023/han00503.asp, https://emergency.cdc.gov/han/2023/han00498.asp.*

[833] *https://oig.hhs.gov/oei/reports/OEI-05-20-00540.asp; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9533809/#:~:text=In%20this%20study%20cohort%2C%2062,%2C%20and%205%25%20were%20Hispanic.*

[834] *https://www.federalregister.gov/documents/2023/01/27/2023-01635/initial-proposals-for-updating-ombs-race-and-ethnicity-statistical-standards.*

[835] Landers S, Kapadia F, Tarantola D. Monkeypox, After HIV/AIDS and COVID–19: Suggestions for Collective Action and a Public Health of Consequence, November 2022. Am J Public Health. 2022 Nov;112(11):1564–1566. doi: 10.2105/AJPH.2022.307100. PMID: 36223580; PMCID: PMC9558195. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9558195/.*

[836] JMIR Preprints #54340: Responding to the return of influenza in the United States: applying CDC surveillance, analysis, and modeling to inform understanding of seasonal influenza.

need data on how respiratory illnesses are affecting and burdening the health care system. Better understanding anticipated impacts empower hospitals and CAHs, health systems, and jurisdictions to take steps that protect patient safety and health care system capacity in the face of surges in respiratory virus cases, including low-probability, high-impact events such as pandemics that pose catastrophic risks to patient safety and the health care system. These include facility-initiated actions, such as delaying elective procedures or activating contracts for additional surge staffing support, as well as jurisdiction or federal-level actions to mobilize supplies, staffing, or other forms of support. Collaborations during the COVID–19 pandemic demonstrated the value of bringing together analysts, public health officials, and health care practitioners and leaders to use advanced analytics to guide emergency response, and data from hospitals were central to some of these efforts.[837] The federal government has made significant investments to consolidate these gains and develop response-ready analytic tools that work at scale to meet the needs of the health care and public health systems.[838]

These proposed requirements would provide a foundation for response-ready hospitals, CAHs, and the broader health system. However, we also recognize that, while necessary, they may not be sufficient in the course of an actual emergency response. Accordingly, we propose that—

- During a declared federal, state, or local PHE for an infectious disease the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.
- During a declared PHE for infectious disease, the Secretary may require the reporting of additional or modified data elements relevant to infectious disease PHE including but not limited to: confirmed infections of the infectious disease, facility structure and infrastructure operational status; hospital/ED diversion status; staffing and staffing shortages; supply inventory shortages (for example, equipment, blood products, gases); medical countermeasures and therapeutics; and additional, demographic factors.
- If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require hospitals to report data up to a daily frequency without notice and comment rulemaking.

We invite comments on if, during a PHE, there should be any limits to the data the Secretary can require without notice and comment rulemaking, such as limits on the duration of additional reporting or the scope of the jurisdiction of reporting (that is, state or local PHEs). We also seek comments on whether and how the Secretary should still seek stakeholder feedback on additional elements during a PHE without notice and comment rulemaking and how HHS should notify hospitals of new required infectious disease data. We also invite comments on the evidence HHS should provide to demonstrate: (1) that an event is ''significantly likely to become a PHE''; or (2) that the increased scope of required data will be used to protect patient and community health and safety. Finally, we invite comment on whether hospitals should be incentivized for this data if the burden of collecting and reporting reaches a certain threshold of cost or time.

6. Collaboration

To further reduce burden in the short term, we will work with the CDC to ensure hospitals can continue to use existing, established systems to report data in the interim. The CDC will continue increasing the automation capabilities of the surveillance systems like NHSN and its ability to connect with other data submission techniques, vendors, and systems. The CDC, CMS, and ASPR are also working with Office of the National Coordinator for Health Information Technology (ONC), jurisdictions, health information technology (health IT) vendors, hospitals and CAHs, and other public and private partners to establish national standards and interoperability requirements that reduce burden and promote standardization. We request comment from facilities on the existing, established data systems; what has worked well and what has been the challenges? Do facilities recommend alternative data reporting mechanisms?

We recognize that some of the proposed data elements are currently reported via multiple mechanisms, and this could place unnecessary burdens on hospitals. If finalized, CMS, CDC, and ASPR will work with hospitals, health systems, and state, territorial, local and tribal agencies (STLTs) to streamline this federal, state, and local reporting burden, utilizing the least burdensome technical exchange mechanism for reporting. CDC and ASPR, together with ONC, would also take steps to encourage state, local, jurisdictional partners to utilize the same HHS-adopted health IT standards like USCDI for data exchange, which would further reduce burden on health care systems. We will also explore where guidance can leverage data sets being developed under the USCDI+ initiative, which focuses on develop and advancing use of standardized data elements for exchange for additional use cases that build on the USCDI.[839]

CMS, CDC, and ASPR recognize the immense value of partnerships with hospitals, health systems, STLTs, associations, and other partners. Throughout the COVID–19 PHE, partners at all levels worked alongside CMS, CDC, and ASPR to provide additional context, insight, and feedback based on conditions on the ground. This context helped data collections be more effective and helped provide a fuller picture than data alone. CMS, CDC, and ASPR are grateful for the many collaborations with partners on data and beyond. CDC, ASPR, and ONC will explore opportunities to codify continued partnerships to prepare for and respond to incidents such as respiratory illnesses more effectively. We welcome public comment on ways that all public agencies involved in these types of data collections can be good partners.

7. Request for Information on Health Care Reporting to the National Syndromic Surveillance Program

CDC's National Syndromic Surveillance Program (NSSP) is a collaboration among CDC, other federal agencies, local and state health departments, and academic and private sector partners who have formed a Community of Practice. They collect, analyze, and share electronic patient encounter data received from emergency departments, urgent and ambulatory care centers, inpatient health care settings, and laboratories.

The electronic health data are integrated through a shared platform; the BioSense Platform. The public health community uses analytic tools on the platform to analyze data received as early as 24 hours after a patient's visit to a participating facility. Public health officials use these timely and actionable data to detect, characterize, monitor, and respond to events of public health concern.

The primary dataset used for analysis is Emergency Department patient visit data obtained through data leveraging

[837] Real-time pandemic surveillance using hospital admissions and mobility data | PNAS Coordinated Strategy for a Model-Based Decision Support Tool for Coronavirus Disease, Utah, USA—Volume 27, Number 5—May 2021—Emerging Infectious Diseases journal—CDC.

[838] *cdc-cfa-annual-report-2023.pdf.*

[839] For more information about USCDI+ *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

HL7v2 ADT-based messaging among CDC, local and state health departments, and the nation's acute care hospitals. By tracking symptoms and diagnoses of patients using this electronic health data source, analysts can detect unusual levels or changing patterns of illness. Every day, more than 2,000 users (analysts at all levels of government including 73 state and local health departments) conduct 4,000 searches of these data for response, decision-making, and action. In 2022–23, these data were used to provide critical insights for more than 40 responses across infectious diseases (including COVID–19, RSV, influenza, tickborne disease, domestic polio, and Mpox), disasters (including hurricanes and typhoons, extreme heat and cold, flooding, chemical exposure, food and water contamination), injuries (including overdose, poisonings, boating injuries in collaboration with the Coast Guard, child abuse and elder abuse) and for mental health, mass gatherings, and other conditions. These data provide public health with a common situational awareness of health threats over time and across regional boundaries. New responses between 2022 and 2023 included the Mpox public health emergency, domestic malaria, asthma from Canadian wildfire smoke, Hurricane Ian, Typhoon Mawar, volcanic eruption in Hawaii, the train derailment in Ohio, hepatitis of unknown cause in children, encephalitis and meningitis in young children, group A Streptococcal Disease, and pertussis. Nationwide, CDC's NSSP data are presented on many local, state, and federal public websites.

CDC's NSSP data provide crucial insights that inform hospital preparedness and better prepare for emerging health events. Syndromic surveillance relies on the secondary use of EHR data that supports delivery of care, enabling an efficient and cost-effective way to identify and characterize public health threats. The provision of these data requires no ongoing action from a health care provider, with data exchange automated from the EHR.

Currently, CDC receives data from 78 percent of the non-federal emergency departments across 50 states, Washington DC, and Guam. In most cases, the technical pathway for these data is from health care facilities' and health care systems' EHRs to their state or local public health agency, which then further shares these data with CDC. However, a number of other options exist, and CDC has worked with Health Information Exchanges, EHR vendors, and individual facilities and health systems to support the technical provisioning of ED data feeds to CDC's NSSP and to supplement the technical capacity of some state and local public health agencies. Recognizing the tremendous value that these data offer in providing a fast and broad look at the trends and patterns of illness and injury across the county, CDC is seeking to close the remaining participation gap to ensure all communities served by acute care hospitals and CAHs are well represented in CDC's NSSP.

The current level of reporting and participation has been the result of many years of active effort by state and local public health agencies, CDC, and hospitals devoted to building a broad network of data providers and program participants. The CMS EHR Incentive Program, and subsequently the Promoting Interoperability Program, have helped to incentivize and offset some of the health care system investment that has been needed for this public health reporting activity to occur. However, some challenges remain in closing the participation gap. In some instances, data are already being shared locally between health care and public health agencies, but they are not yet provided to the national system, CDC's NSSP. In other cases, some health care facilities have not yet begun providing data despite their jurisdictional public health agency already actively participating in CDC's NSSP.

Syndromic surveillance is not a part of any condition of participation under this program, but the continued growth of national syndromic surveillance would benefit hospitals, health care, and public health. The goal of this RFI is better understand what else can be done to ensure that this effort can continue to make progress and that this critical data source is available at all levels of public health to support health care preparedness, public health readiness, and responsiveness to existing and emerging health threats. We seek input on the following:

- How can CMS further advance hospital and CAH participation in CDC's NSSP?
- Should CMS require hospitals and CAHs to report data to CDC's NSSP, whether as a condition of participation or as a modification to current requirements under the Promoting Interoperability Program?
- Should CMS explore other incentive or existing quality and reporting programs to collect this information?
- What would be the potential burden for facilities in creating these connections in state and local public health jurisdictions that have not yet established syndromic programs and/or where state and local public health are not presently exchanging data with CDC's NSSP? Are there unique challenges in rural areas that CMS should take into consideration?
- Data reported as part of syndromic surveillance requirements could serve as an alternative source for the COVID–19, influenza, and RSV hospitalization reporting requirements proposed in this rule—and even support eventual evolution towards an all-hazards approach for monitoring inpatient hospitalizations for conditions of public health significance. Should CMS consider a future requirement or otherwise incentivize facilities to expand ADT-based reporting currently provided for emergency department visits to include data collected from inpatient settings as defined in the HHS COVID–19 reporting guidance,[840] or a subset of these? If the latter, should a subset of inpatient locations be subject to such a requirement? What would be the potential value and burden trade-offs to facilities? And, should any requirement specify that reporting also be to CDC's NSSP (in addition to more general reporting to state/local syndromic surveillance systems? (noting that often the reporting to CDC's NSSP happens through a given state/local system and that applicable law may apply).
- How can CMS leverage its authorities and programs to improve the quality of data reported to CDC's NSSP, especially for key elements that are sometimes incomplete, including discharge diagnoses, discharge disposition, and patient class? [841]
- In addition to its value for public health, how could CDC's NSSP serve as a tool to directly improve clinical practice, patient safety, and overall situational awareness? What types of questions would you like the system to help answer?

XI. MedPAC Recommendations and Publicly Available Files

A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have

[840] *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf.*

[841] *https://www.cdc.gov/nssp/technical-pubs-and-standards.html#Dictionaries.*

reviewed MedPAC's March 2024 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2025 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov.*

B. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2021 Medicare cost reports used to create the proposed FY 2025 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4. of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2007 through FY 2025 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2022 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4 of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2025 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2025 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2005 through FY 2025.

5. FY 2025 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2025 proposed rule home page or the FY 2025 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2025 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: internet at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.*

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2025.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2025 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2025 IPPS Update.

11. AOR/BOR File

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR file are ''Before Outliers Removed'' and the AOR file is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2025 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2025 proposed rule home page or the FY 2025 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2025 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2025 proposed rule home page or the FY 2025 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2025 IPPS Update.

14. Hospital Readmissions Reduction Program Supplemental File

The Hospital Readmissions Reduction Program Supplemental File is only available and updated for the final rule, when the most recent data is available. Therefore, we refer readers to the FY 2024 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2025 IPPS/LTCH PPS proposed rule supplemental file.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2025 proposed rule home page or the FY 2025 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2025 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for DSH-eligible hospitals as well as the supplemental payments for eligible IHS and Tribal hospitals and hospitals located in Puerto Rico for FY 2025. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments, estimated per-claim uncompensated care payment amounts, and if applicable, supplemental payment amounts. The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2025 proposed rule home page or the FY 2025 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2025 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.) Two versions of this file are created each year to support rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: For FY 2025 and FY 2026 applications.

XII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The following ICRs are listed in the order of appearance within the preamble (see sections II. through X. of the preamble of this proposed rule).

B. Collection of Information Requirements

1. ICRs Regarding the Implementation of Section 4122 of the Consolidated Appropriations Act, 2023—Distribution of Additional Residency Positions

As discussed in section V.G.2. of the preamble of this proposed rule, teaching hospitals would be able to submit electronic applications to CMS for resident slot increase requests under section 4122 of the Consolidated Appropriations Act (CAA), 2023. The burden associated with these requests will be captured under OMB control number 0938–1417 (expiration date March 31, 2025), currently approved for CMS to receive electronic applications for Medicare-funded GME Residency Positions submitted in accordance with Section 126 of the CAA, 2021. For that information collection, we estimated each eligible hospital (1,325 hospitals) would require 8 hours per eligible hospital annually to gather appropriate documentation, prepare and submit an application for a total burden of 10,600 hours (8 hours × 1,325 hospitals). The most recent data from the BLS reflects a mean salary for legal secretaries and administrative assistants of $26.05.[842] With the fringe benefits included the salary is $52.10 ($26.05 × 2). The total cost related to this information collection is approximately $416.80 per eligible hospital per year ($52.10 × 8.0 hours per hospital). The total estimated burden is $552,260 ($52.10 × 10,600 hours). As a result of the proposed policies in this proposed rule, for FY 2026, if an eligible hospital submits an electronic application to CMS for section 126 of the CAA, 2021 or for section 4122 of the CAA, 2023, the total annual burden remains the same. However, if an eligible hospital submits an electronic application to CMS for both section 126 of the CAA, 2021, and section 4122 of the CAA, 2023, we estimate that the new total annual burden to be 16 hours per eligible hospital. We estimate the adjustment in the number of hours from 8 hours to 16 hours, results in 21,200 hours (16 hours × 1,325 hospitals) at a cost of $1,104,520 ($52.10 × 21,200 hours) for FY 2026 only. We will submit the revised information collection request to OMB for approval under OMB control number 0938–1417 (expiration date March 31, 2025).

2. ICRs for Payment Adjustments for Establishing and Maintaining Access to Essential Medicines

In section V.J. of the preamble of this proposed rule, we are proposing, for cost reporting periods beginning on or after October 1, 2024, a separate payment under IPPS to small, independent hospitals for establishing and maintaining access to buffer stocks of essential medicines to foster a more reliable, resilient supply of these medicines for these hospitals. The proposed payment adjustments would be based on the reasonable cost incurred by the hospital for establishing and maintaining access to a 6-month buffer stock of one or more essential medicines during the cost reporting period. In order to calculate the essential medicines payment adjustment for each eligible cost reporting period, we propose to create a new supplemental cost reporting form that would collect the additional information from hospitals.

Specifically, the new cost reporting worksheet would only collect the costs of a hospital that voluntarily requests separate payment under this proposed policy for the costs associated with establishing and maintaining access to its buffer stock of one or more essential medicines. This new information would include the costs associated with contractual arrangements to establish and maintain access to buffer stock(s) of essential medicine(s) as well as the costs associated with directly establishing and maintaining buffer stock(s) of essential medicine(s) such as (but not limited to) utilities like cold chain storage and heating, ventilation, and air conditioning, warehouse space, refrigeration, management of stock including stock rotation, managing expiration dates, and managing recalls, administrative costs related to contracting and record-keeping, and dedicated staff for maintaining the buffer stock(s). This information would be used, along with other information already collected on the Hospitals and Health Care Complex Cost Report (Form CMS–2552–10) approved under OMB control number 0938–0050, to calculate the IPPS payment adjustment amount. This new cost report worksheet may be submitted by a provider of service as part of the annual filing of the cost report and the provider should make available to its contractor and CMS, documentation to substantiate the data included on this Medicare cost report worksheet. The documentation requirements are based on the recordkeeping requirements at current § 413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under Medicare.

The burden associated with filling out this new essential medicine cost report worksheet would be the time and effort necessary for the provider to locate and obtain the relevant supporting documentation to report the costs of a hospital to establish and maintain access to its buffer stock for the cost reporting period. We estimate the number of respondents to be 493. This number is comprised of Medicare certified section 1886(d) hospitals that are small, independent hospitals that would be eligible for the proposed payment adjustment. We estimate the average burden hours per facility to be 1.0 hour. This breaks down to approximately 0.4 hours per provider for recordkeeping, which includes a 0.10-hour burden associated with monitoring the FDA Drug Shortage Database once when the hospital elects to establish a buffer stock of an essential medicine and again when the hospital is not able to maintain a previously established 6-month buffer stock of an essential medicine. We estimate 0.6

[842] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Legal Secretaries and Administrative Assistants. Accessed on February 6, 2024. Available at: *https://www.bls.gov/oes/current/oes436012.htm.*

hour per provider for obtaining and analyzing the data and reporting. We recognize this average varies depending on the provider size and complexity. In addition to seeking general comment on this burden estimate, we are specifically seeking feedback on the burden estimate that is associated with monitoring the FDA shortage list as described. CMS would conduct provider education regarding additions and deletions to the publicly available FDA Drug Shortages Database to assist hospitals with this proposed policy.

We estimate the associated labor costs as follows. As explained earlier, the estimate of 0.4 hour is required for recordkeeping including time for bookkeeping activities. Based on the most recent data published by Bureau of Labor Statistics (BLS) in its 2022 Occupation Employment and Wage Statistics Program, the mean hourly wage for Bookkeeping, Accounting, and Auditing Clerks (Category 43–3031) is $22.81. We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $45.62 ($22.81 + $22.81) and multiplied it by 0.4 hour, to determine the annual recordkeeping costs per hospital to be $18.25 ($45.62 per hour multiplied by 0.4 hour). The estimated 0.6 hours for reporting include time for accounting and audit professionals' activities. The mean hourly wage for Accountants and Auditors (Category 13–2011) is $41.70. We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $83.40 ($41.70 plus $41.70) and multiplied it by 0.6 hour, to determine the annual reporting costs per hospital to be $50.04 ($83.40 per hour multiplied by 0.6 hour). We calculated the total average annual cost per hospital of $68.29 by adding the recordkeeping costs (which includes monitoring the FDA Drug Shortages Database) of $18.25 plus the reporting costs of $50.04. We estimated the total annual cost to be $33,667 ($68.29 cost per hospital multiplied by 493 hospitals). We seek comment on our estimates and cost of recordkeeping and oversight.

3. ICRs Relating to the Hospital Readmissions Reduction Program

In this proposed rule, we are not proposing any changes to the Hospital Readmissions Reduction Program for FY 2025. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

4. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IX.B.2. of the preamble of this proposed rule, we discuss our proposed updates to the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt an updated version of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure beginning with the FY 2030 program year to align with the proposed adoption of the updated measure in the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination. The proposed updated HCAHPS Survey measure in the Hospital VBP Program would add three new survey dimensions, remove one existing survey dimension, and modify one existing survey dimension. We are also proposing to modify scoring on the HCAHPS Survey measure beginning with the FY 2030 program year to account for the proposed updates to the survey. We are also proposing to modify scoring of the HCAHPS Survey measure in the Hospital VBP Program for the FY 2027 to FY 2029 program years to only score on the six unchanged dimensions of the survey while the updates to the survey are adopted and publicly reported on in the Hospital IQR Program.

Data collections for the Hospital VBP Program are associated with the Hospital IQR Program under OMB control number 0938–1022 (expiration date January 31, 2026), the National Healthcare Safety Network under OMB control number 0920–0666 (expiration date December 31, 2026), and the HCAHPS Survey under OMB control number 0938–0981 (expiration date January 31, 2025). The Hospital VBP Program would use data that are also used to calculate quality measures in these programs and Medicare FFS claims data that hospitals are already submitting to CMS for payment purposes, therefore, the program does not anticipate any additional change in burden associated with these proposed updates outside of the burden that is associated with collecting that data under the Hospital IQR Program. There is also no estimated change in burden related to the proposed scoring methodology change because the proposal does not require hospitals to submit any additional information specific to the Hospital VBP Program but instead would change how hospitals are scored based on the information already being submitted under the Hospital IQR Program.

We discuss the burden associated with the similar proposal to adopt the updated HCAHPS Survey measure under the Hospital IQR Program in section XII.B.6. of the preamble of this proposed rule. We note that respondents would only complete the HCAHPS Survey once for use in both programs, so there is no additional information collection burden for the Hospital VBP Program.

5. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

OMB has currently approved 28,800 hours of burden and approximately $1.2 million under OMB control number 0938–1352 (expiration date November 30, 2025), accounting for information collection burden experienced by 400 subsection (d) hospitals selected for validation each year in the HAC Reduction Program.

In section V.M. of the preamble of this proposed rule, we state that we are not proposing to add or remove any measures from the HAC Reduction Program.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

Data collections for the Hospital IQR Program are associated with OMB control number 0938–1022. OMB has currently approved 2,286,977 hours of burden at a cost of approximately $80.3 million under OMB control number 0938–1022 (expiration date January 31, 2026), accounting for information collection burden experienced by approximately 3,150 IPPS hospitals and 1,350 non-IPPS hospitals for the FY 2026 payment determination. In this proposed rule, we describe the burden changes regarding collection of information, under OMB control number 0938–1022, for IPPS hospitals.

For more detailed information on our proposals for the Hospital IQR Program, we refer readers to sections IX.B.1., IX.B.2., and IX.C. of the preamble of this proposed rule. We are proposing to adopt seven new measures: (1) Age-Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (2) Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (3) Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the

CY 2026 reporting period/FY 2028 payment determination; (4) Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 reporting period; (5) Hospital Harm—Falls with Injury electronic clinical quality measure (eCQM) beginning with the CY 2026 reporting period/FY 2028 payment determination; (6) Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; and (7) Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination. We are proposing refinements to two measures: (1) the Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination; and (2) the HCAHPS Survey beginning with the CY 2025 reporting period/FY 2027 payment determination. We are proposing to remove five measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination; (2) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (3) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (4) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; and (5) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2021–March 31, 2024 reporting period which is associated with the FY 2026 payment determination. We are proposing to increase the total number of eCQMs reported from six to nine for the CY 2026 reporting period/FY 2028 payment determination and then from nine to eleven beginning with the CY 2027 reporting period/FY 2029 payment determination. Lastly, we are proposing to update the scoring methodology for eCQM validation, to remove the requirement that hospitals must submit 100 percent of eCQM records to pass validation beginning with CY 2025 eCQM data affecting the FY 2028 payment determination, and to no longer require hospitals to resubmit medical records as part of their request for reconsideration of validation beginning with CY 2025 discharges affecting the FY 2028 payment determination.

In the FY 2024 IPPS/LTCH PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital IQR Program (88 FR 59312). Using the most recent data the May 2022 National Occupational Employment and Wage Estimates (OEWS) from the BLS reflects a mean hourly wage of $24.56 per hour for all medical records specialists (SOC 29–2072), however, we are proposing to use the mean hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $26.06.[843] We believe the industry of ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $52.12 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59312), our burden estimates were based on an assumption of approximately 3,150 IPPS hospitals. For this proposed rule, based on data from the FY 2024 Hospital IQR Program payment determination, we are updating our assumption and estimate that approximately 3,050 IPPS hospitals will report data to the Hospital IQR Program for the CY 2025 reporting period.

[843] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed January 3, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

b. Information Collection Burden Estimate for the Proposed Adoption of the Age-Friendly Hospital Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

In section IX.C.5.a. of the preamble of this proposed rule, we discuss the proposal to adopt the Age-Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment determination. Hospitals would submit responses on an annual basis during the submission period through CMS' Hospital Quality Reporting (HQR) System. Specifically, for the Age-Friendly Hospital measure, hospitals would be required to attest ''yes'' or ''no'' in response to questions across five domains annually for a given reporting period. Similar to the Hospital Commitment to Health Equity measure currently approved under OMB control number 0938–1022 (expiration date January 31, 2026), which also requires a ''yes'' or ''no'' attestation to questions across five domains, we estimate the information collection burden associated with this measure to be, on average across all 3,050 IPPS hospitals, no more than 10 minutes per hospital per year (87 FR 49385). Using the estimate of 10 minutes (or 0.167 hour) per hospital per year, we estimate that the adoption of this measure would result in a total annual burden increase of 509 hours across all participating IPPS hospitals (0.167 hour × 3,050 IPPS hospitals) at a cost of $26,529 (509 hours × $52.12).

c. Information Collection Burden Estimate for the Proposed Adoption of the Patient Safety Structural Measure Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

In section IX.B.1. of the preamble of this proposed rule, we discuss the proposal to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination. Hospitals would submit responses on an annual basis during the submission period through the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). Specifically, hospitals would be required to provide responses and attest ''yes'' or ''no'' in response to a total of five domains for a given reporting period. Similar to the Hospital Commitment to Health Equity measure currently approved under OMB control

number 0938–1022 (expiration date January 31, 2026), which also requires a ''yes'' or ''no'' response to each of five domains, we estimate the information collection burden associated with this measure to be, on average across all 3,050 IPPS hospitals, no more than 10 minutes per hospital per year. Using the estimate of 10 minutes (or 0.167 hour) per hospital per year, and the updated wage estimate as described previously, we estimate that the adoption of this measure would result in a total annual burden increase of 509 hours across all participating IPPS hospitals (0.167 hour × 3,050 IPPS hospitals) at a cost of $26,529 (509 hours × $52.12).

We discuss the burden associated with the proposal to adopt the Patient Safety Structural measure for the PCHQR Program in section XII.B.7.a. We will submit the revised information collection estimates to OMB for approval under OMB control number 0920–0666.

d. Information Collection Burden Estimate for the Proposed Adoption of Two Healthcare-Associated Infection (HAI) Measures Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

In section IX.C.5.b. of the preamble of this proposed rule, we are proposing to adopt two HAI measures beginning with the CY 2026 reporting period/FY 2028 payment determination: (1) the CAUTI Standardized Infection Ratio Stratified for Oncology Locations measure, and (2) the CLABSI Standardized Infection Ratio Stratified for Oncology Locations measure. We are proposing to collect data for both measures via the National Healthcare Safety Network (NHSN), which is a secure, internet-based surveillance system maintained and managed by the CDC that is provided free of charge to providers. To report to the NHSN, hospitals must first agree to the NHSN Agreement to Participate and Consent form, which specifies how NHSN data will be used, including fulfilling CMS's quality measurement reporting requirements for NHSN data.[844] Hospitals would provide data for both measures from their EHRs and report on a quarterly basis. The burden associated with submission of data via the NHSN continues to be accounted for under OMB control number 0920–0666 (expiration date December 31, 2026). Therefore, we do not anticipate any changes in burden associated with OMB control number 0938–1022.

[844] CDC. (2023). FAQs About NHSN Agreement to Participate and Consent. Available at: *https://www.cdc.gov/nhsn/about-nhsn/faq-agreement-to-participate.html.*

e. Information Collection Burden for the Proposed Adoption of Two eCQMs and Modification of One eCQM Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

In sections IX.C.5.c. and IX.C.5.d of the preamble of this proposed rule, we are proposing to adopt two new eCQMs beginning with the CY 2026 reporting period/FY 2028 payment determination: (1) the Hospital Harm—Falls With Injury eCQM, and the (2) Hospital Harm—Postoperative Respiratory Failure eCQM, to add to the set of eCQMs from which hospitals may self-select to meet their eCQM reporting requirements. In section IX.C.7.a. of the preamble of this proposed rule, we are proposing to modify the GMCS eCQM to add patients ages 18 to 64 to the current cohort of patients 65 years or older beginning with the CY 2026 reporting period/FY 2028 payment determination.

Under OMB control number 0938–1022 (expiration date January 31, 2026), the currently approved burden estimate for reporting and submission of eCQM measures is one hour per quarter per IPPS hospital (0.167 hours/eCQM x 6 eCQMs) for all six required eCQM measures. The addition of these two new eCQMs and modification of the GMCS eCQM would not affect the information collection burden associated with submitting eCQM measure data under the currently established Hospital IQR Program, which is that hospitals are not required to report more than a total of six eCQMs (87 FR 49299 through 49302). However, in the immediately following section of this Collection of Information section, we discuss the burden associated with our proposal to increase the total number of eCQMs.

f. Information Collection Burden for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

In section IX.C.9.c. of the preamble of this proposed rule, we are proposing to modify the eCQM reporting and submission requirements whereby we would increase the total number of eCQMs to be reported from six to nine eCQMs for the CY 2026 reporting period/FY 2028 payment determination and then from nine to eleven eCQMs beginning with the CY 2027 reporting period/FY 2029 payment determination.

We previously finalized in the FY 2023 IPPS/LTCH PPS final rule that, for the CY 2024 reporting period/FY 2026 payment determination and subsequent years, hospitals are required to submit data quarterly for six eCQMs each year which must include the Safe Use of Opioids-Concurrent Prescribing, Cesarean Birth, and Severe Obstetric Complications eCQMs in addition to three self-selected eCQMs (87 FR 49387). In this proposed rule, we are proposing that, for the CY 2026 reporting period/FY 2028 payment determination, hospitals would be required to submit data for nine total eCQMs: three self-selected, Safe Use of Opioids, Severe Obstetric Complications, Cesarean Birth, Hospital Harm—Severe Hypoglycemia, Hospital Harm—Severe Hyperglycemia, and Hospital Harm—Opioid-Related Adverse Events. We are also proposing that, beginning with the CY 2027 reporting period/FY 2029 payment determination, hospitals would be required to submit data for these nine eCQMs as well as the Hospital Harm—Pressure Injury and Hospital Harm—Acute Kidney Injury eCQMs.

We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. For the increase in submission from six to nine eCQMs for the CY 2026 reporting period/FY 2028 payment determination, we estimate a total of 30 minutes or 0.5 hour (10 minutes × 3 eCQMs) per hospital per quarter. We estimate a total burden increase of 6,100 hours (0.5 hour x 3,050 IPPS hospitals × 4 quarters) at a cost of $317,932 (6,100 hours × $52.12). For the additional increase in submission from nine to eleven eCQMs beginning with the CY 2027 reporting period/FY 2029 payment determination, we estimate a total of 50 minutes or 0.83 hours (10 minutes × 5 eCQMs) per hospital per quarter, accounting for both the increase of three eCQMs for the CY 2026 reporting period/FY 2028 payment determination and the increase of two eCQMs for the CY 2027 reporting period/FY 2029 payment determination. We estimate a total burden increase of 10,126 hours annually (0.83 hour × 3,050 IPPS hospitals x 4 quarters) at a cost of $527,767 (10,126 hours × $52.12) compared to the currently approved burden estimate.

g. Information Collection Burden for the Proposed Adoption of Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients With Complications (Failure-to-Rescue) Measure Beginning with the July 1, 2023—June 30, 2025 Reporting Period/FY 2027 Payment Determination

In section IX.C.5.e. of the preamble of this proposed rule, we are proposing to adopt the Thirty-day Risk-standardized Death Rate among Surgical Inpatients

with Complications (Failure-to-Rescue) claims measure beginning with the July 1, 2023—June 30, 2025 reporting period/FY 2027 payment determination. Because this measure is calculated using Medicare Advantage data and Medicare FFS claims that are already reported to the Medicare program for payment purposes, adopting this measure would not result in a change in burden associated with OMB control number 0938–1022 (expiration date January 31, 2026).

h. Information Collection Burden for the Proposed Removal of Four Payment Measures and One Claims-Based Measure

In section IX.C.6.b. of the preamble of this proposed rule, we are proposing to remove four claims-based payment measures beginning with the FY 2026 payment determination: (1) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI measure; (2) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for HF measure; (3) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia measure; and (4) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary THA and/or TKA measure. In section IX.C.6.a., we are also proposing to remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) claims-based measure beginning with the FY 2027 payment determination.

Because these measures are calculated using Medicare FFS claims that are already reported to the Medicare program for payment purposes, removing these measures would not result in a change in burden associated with OMB control number 0938–1022.

i. Information Collection Burden for the Proposed Modification of the HCAHPS Survey Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

In section IX.B.2.e.of the preamble of this proposed rule, we are proposing to modify the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 program year. Specifically, the updated measure includes adding three new sub-measures, removing one existing sub-measure, and revising one existing sub-measure. The new sub-measures would include: ''Care Coordination,'' ''Restfulness of Hospital Environment,'' and ''Information about Symptoms.''

Under OMB control number 0938–0981 (expiration date January 31, 2025), we estimate the time to complete the HCAHPS Survey is approximately 7.25 minutes per respondent and approximately 2,309,985 respondents would complete and submit the HCAHPS Survey as part of the Hospital IQR Program. As stated in section IX.B.2.b. of this proposed rule, we estimate the combination of survey sub-measure removals and additions would result in an additional 0.75 minute (0.0125 hour) per respondent to complete the updated version of the HCAHPS Survey. Therefore, we estimate the updated time to complete the HCAHPS Survey would be 8 minutes per respondent (0.133 hour).

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.04/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.[845] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers from BLS's Labor Force Statistics program, Current Population Survey (CPS) of $1,118, divided by 40 hours to calculate an hourly pre-tax wage rate of $27.95/hr.[846] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[847] resulting in the post-tax hourly wage rate of $24.04/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. We therefore estimate a burden increase of 28,875 hours (2,309,985 respondents × 0.0125 hour) at a cost of $694,155 (28,875 hours × $24.04).

We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–0981.

[845] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[846] *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed January 1, 2024.

[847] *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed January 2, 2024.

j. Information Collection Burden for the Proposed Changes to Data Validation Policies

In section IX.C.10. of the preamble of this proposed rule, we are proposing to update the scoring methodology for eCQM validation, replace the existing combined validation score for eCQMs and chart-abstracted measures with two separate validation scores for chart-abstracted measures and eCQMs beginning with the FY 2028 payment determination, and remove the requirement that hospitals must submit 100 percent of eCQM records to pass validation beginning with CY 2025 eCQM data affecting the FY 2028 payment determination. We are also proposing in section IX.C.13 of this proposed rule to no longer require hospitals to resubmit medical records as part of their request for reconsideration of validation, beginning with CY 2025 discharges affecting the FY 2028 payment determination.

Proposed changes to the scoring methodology and validation score would not affect burden as neither the amount of data nor frequency of data submission is impacted. The proposal to remove the requirement that hospitals must submit 100 percent of eCQM records to pass validation would not affect burden, as the proposal to implement eCQM validation scoring would still require hospitals to submit the same number of requested medical records to validate the accuracy of eCQM data (the extent to which data abstracted from the submitted medical record matches the data submitted in the QRDA I file). Lastly, as finalized in the FY 2011 IPPS/LTCH PPS final rule regarding information collection burden associated with the Hospital IQR Program's request for reconsideration process, information collection requirements imposed subsequent to an administrative action are not subject to the Paperwork Reduction Act (PRA) under 5 CFR 1320.4(a)(2), therefore the proposal to no longer require hospitals to resubmit medical records as part of their request for reconsideration of validation would not affect burden (75 FR 50411).

k. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022 (expiration date January 31, 2026), we estimate that the policies promulgated in this proposed rule would result in a total increase of 10,635 hours at a cost of $554,296 annually for 3,050 IPPS hospitals from the CY 2025 reporting period/FY 2027

payment determination through the CY 2027 reporting period/FY 2029 payment determination. Under OMB control number 0920–0666 (expiration date December 31, 2026), we estimate that the policies being proposed in this proposed rule would result in a total increase of 509 hours at a cost of $26,529 annually for 3,050 IPPS hospitals beginning with the CY 2025 reporting period/FY 2027 payment determination. Under OMB control number 0938–0981 (expiration date January 31, 2025), we estimate that the policies promulgated in this proposed rule would result in a total increase of 28,875 hours at a cost of $694,155 annually for 3,050 hospitals beginning with the CY 2025 reporting period/FY 2027 payment determination. The total increase in burden associated with the proposed information collections under OMB control numbers 0938–1022, 0920–0666, and 0938–0981 is approximately 40,019 hours (10,635 + 509 + 28,875) at a cost of $1,274,980 ($554,296 + $26,529 + $694,155). We will submit the revised information collection estimates to OMB for approval under OMB control numbers 0938–1022, 0920–0666, and 0938–0981.

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.K. of Appendix A of this proposed rule).

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TABLE XII.B-01: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE ASSOCIATED WITH OMB CONTROL #0938-1022 FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2025 Reporting Period / FY 2027 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per hospital	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Age-Friendly Hospital Measure	10	1	3,050	1	0.167	509	N/A	+509
Total Change in Information Collection Burden Hours: +509								
Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+509) = **$26,529**								

TABLE XII.B-02: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE ASSOCIATED WITH OMB CONTROL #0938-1022 FOR THE CY 2026 REPORTING PERIOD/FY 2028 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2026 Reporting Period / FY 2028 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Age-Friendly Hospital Measure	10	1	3,050	1	0.167	509	N/A	+509
Adopt Modification to eCQM Reporting	90	4	3,050	9	1.5	18,300	12,200	+6,100
	Total Change in Information Collection Burden Hours: +6,609							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+6,609) = **$344,461**							

TABLE XII.B-03: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE ASSOCIATED WITH OMB CONTROL #0938-1022 FOR THE CY 2027 REPORTING PERIOD/FY 2029 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2027 Reporting Period / FY 2029 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Age-Friendly Hospital Measure	10	1	3,050	1	0.167	509	N/A	+509
Adopt Modification to eCQM Reporting	110	4	3,050	11	1.83	22,326	12,200	+10,126
	Total Change in Information Collection Burden Hours: +10,635							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+10,635) = **$554,296**							

TABLE XII.B-04: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE ASSOCIATED WITH OMB CONTROL #0920-0666 FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-0666 for the CY 2025 Reporting Period / FY 2027 Payment Determinations								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per hospital	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Patient Safety Structural Measure	10	1	3,050	1	0.167	509	N/A	+509
	Total Change in Information Collection Burden Hours: +509							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+509) **= $26,529**							

TABLE XII.B-05: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE ASSOCIATED WITH OMB CONTROL #0938-0981 FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-0981 for the FY 2027 Payment Determination								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Proposed Measure Updates to the HCAHPS Survey	8	1	2,309,985	1	0.133	307,998	279,123	+28,875
	Total Change in Information Collection Burden Hours: +28,875							
	Total Cost Estimate: Updated Hourly Wage ($24.04) x Change in Burden Hours (+28,875) = **$694,155**							

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7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

OMB has currently approved 109 hours of burden at a cost of $2,452 under OMB control number 0938–1175 (expiration date January 31, 2027), accounting for the annual information collection requirements for 11 PCHs for the PCHQR Program. In the preamble of this proposed rule, we are proposing to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year, which we anticipate would affect the information collection burden. We are also proposing to modify the HCAHPS survey beginning with the CY 2025 reporting period/FY 2027 program year, which is currently approved under OMB control number 0938–0981 (expiration date January 31, 2025). We are also proposing to move up the start date for public display of the Hospital Commitment to Health Equity (HCHE) measure. This proposal would not affect the information collection burden associated with the PCHQR Program.

In the FY 2024 IPPS/LTCH PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the PCHQR Program (88 FR 59317). While the most recent data from the BLS reflects a mean hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the mean hourly wage for "general medical and surgical

hospitals,'' which is an industry within medical records specialists.[848] We believe the industry of ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $52.12 per hour throughout the discussion in this section of this rule for the PCHQR Program.

a. Information Collection Burden Estimate for the Proposal To Adopt the Patient Safety Structural Measure Beginning With the CY 2025 Reporting Period/FY 2027 Program Year

In section IX.B.1. of the preamble of this proposed rule, we discuss the proposal to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year. PCHs would submit responses on an annual basis during the submission period through the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). Specifically, PCHs would be required to provide responses and attest ''yes'' or ''no'' in response to a total of five domains for a given reporting period. Similar to the Hospital Commitment to Health Equity measure currently approved under OMB control number 0938–1022 (expiration date January 31, 2026), which also requires a yes or no response to each of five domains, we estimate the information collection burden associated with this measure to be, on average across all 11 PCHs, no more than 10 minutes per PCH per year. Using the estimate of 10 minutes (or 0.167 hours) per PCH per year, and the updated wage estimate as described previously, we estimate that the adoption of this measure would result in a total annual burden increase of 2 hours across all participating PCHs (0.167 hours × 11 PCHs) at a cost of $104 (2 hours × $52.12).

We discuss the burden associated with the proposal to adopt the Patient Safety Structural measure for the Hospital IQR Program in section XII.B.6.c. of the preamble of this proposed rule. We will submit the revised information collection estimates to OMB for approval under OMB control number 0920–0666.

b. Information Collection Burden for the Proposed Modification of the HCAHPS Survey Beginning With the CY 2025 Reporting Period/FY 2027 Program Year

In section IX.B.2.e of the preamble of this proposed rule, we are proposing to modify the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 program year. Specifically, we are proposing to refine the current HCAHPS Survey by adding three new sub-measures, removing one existing sub-measure, and revising one existing sub-measure. The new sub-measures would include: ''Care Coordination,'' ''Restfulness of Hospital Environment,'' and ''Information about Symptoms.''

Under OMB control number 0938–0981 (expiration date January 31, 2025), we estimate the time to complete the HCAHPS Survey is approximately 7.25 minutes per respondent and approximately 13,105 respondents would complete and submit the HCAHPS survey as part of the PCHQR Program. As stated in section IX.B.2.b of this proposed rule, we estimate the combination of sub-measure removals and additions would result in an additional 0.75 minutes (0.0125 hours) per respondent to complete the HCAHPS Survey. Therefore, we estimate the updated time to complete the HCAHPS Survey would be 8.0 minutes per respondent (0.133 hours).

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.04/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.[849] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,118, divided by 40 hours to calculate an hourly pre-tax wage rate of $27.95/hr. [850] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[851] resulting in the post-tax hourly wage rate of $24.04/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. We therefore estimate a burden increase of 164 hours (13,105 respondents × 0.0125 hours) at a cost of $3,943 (164 hours × $24.04).

We will submit the revised information collection request to OMB for approval under OMB control number 0938–0981.

c. Information Collection Burden Estimate for the Proposal To Move Up the Start Date of Public Display of the Hospital Commitment to Health Equity Measure

In section IX.D.5. of the preamble of this proposed rule, we are proposing to move up the start date of PCH performance on the Hospital Commitment to Health Equity measure. Because we are not proposing to require PCHs to collect or submit any additional data, we do not estimate any change in information collection burden associated with this proposal.

d. Summary of Information Collection Burden Estimates for the PCHQR Program

In summary, under OMB control number 0920–0666 (expiration date December 31, 2026), we estimate that the policies being proposed in this proposed rule would result in a total increase of 2 hours at a cost of $104 annually for 11 PCHs beginning with the CY 2025 reporting period/FY 2027 program year. Under OMB control number 0938–0981 (expiration date January 31, 2025), we estimate that the policies being proposed in this proposed rule would result in a total increase of 164 hours at a cost of $3,943 annually for 11 PCHs beginning with the CY 2025 reporting period/FY 2027 program year. The total increase in burden associated with this information collection would be approximately 166 hours at a cost of $4,047. We will submit the revised information collection request to OMB for approval under OMB control numbers 0920–0666 and 0938–0981.

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[848] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on January 2, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

[849] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[850] *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed January 1, 2024.

[851] *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed January 2, 2024.

TABLE XII.B-05: SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/FY 2027 PROGRAM YEAR

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-0666 for the CY 2025 Reporting Period/FY 2027 Program Year								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Proposed Annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Adopt Patient Safety Structural Measure	10	1	11	1	0.167	2	N/A	+2
	Total Change in Information Collection Burden Hours: +2							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+2) = **$104**							

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8. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

An LTCH that does not meet the requirements of the LTCH QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual update for that fiscal year.

We believe that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. In sections IX.E.4.c. and IX.E.4.e. of the preamble of this proposed rule, we proposed to add four items to the LCDS and replace one item on the LCDS. The

TABLE XII.B-06: SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/FY 2027 PROGRAM YEAR

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-0981 for the CY 2025 Reporting Period/FY 2027 Program Year								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Proposed Annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Adopt Proposed Measure Updates to the HCAHPS Survey	0.75	1	13,105	1	0.133	1,747	1,583	+164
	Total Change in Information Collection Burden Hours: +164							
	Total Cost Estimate: Updated Hourly Wage ($24.04) x Change in Burden Hours (+164) = **$3,943**							

LCDS V5.1 has been approved under OMB control number 0938–1163 (Expiration date: 08/31/2025). The following is a discussion of this information collection.

In section IX.E.4.c. of the preamble of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category beginning with the FY 2028 LTCH QRP. The proposed items, Living Situation (one item), Food (two items), and Utilities (one item), would be collected at admission using the LCDS. If adopted as proposed, four new items would be added to the LCDS and would result in an increase of 0.02 hours (1.2 minutes/60) of clinical staff time at admission. We are also proposing to modify the current Transportation item on the LCDS, which is currently collected at admission and discharge. We are proposing that the Transportation item would only be collected at admission beginning with the FY 2028 LTCH QRP as described in sections IX.E.4.e. and E.7.b. of the preamble of this proposed rule. The burden associated with collecting this item at admission and discharge was accounted for in the FY 2020 IPPS/LTCH final rule (84 FR 42606) when the item was originally adopted. If adopted as proposed, LTCHs would no longer have to collect one item at discharge to meet LTCH QRP reporting requirements, which would result in a decrease of 0.005 hours (0.3 minutes/60) of clinical staff time at discharge. Using data collected for FY 2023, we estimated 130,050 total admissions and 96,890 planned discharges from 329 LTCHs annually. This equates to an increase of 2,117 hours for all LTCHs [(130,050 × 0.02 hour) − (96,890 × 0.005 hour)] and 6.43 hours per LTCH.

We believe that the additional SDOH items would be completed equally by RNs and LPN/LVNs. Individual LTCHs determine the staffing resources necessary. We averaged BLS' National Occupational Employment and Wage Estimates (see Table XII.B–05) for these labor types and established a composite cost estimate using our adjusted wage estimates. The composite estimate of $65.31/hr was calculated by weighting each hourly wage equally [($78.10 + $52.52)/2]. We estimate the total cost would be increased by $420.16 per LTCH annually, or $138,231.88 for all LTCHs annually ([(130,050 admission assessments × 0.02 hour = 2,601 hours) × $65.31/hr] − [(96,890 planned discharge assessments × 0.005 hour = 484.45 hours) × $65.31/hr] = $138,231.88); ($138,231.88/329 LTCHs = $420.16/LTCH).

TABLE XII.B-05: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2021 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$39.05	$39.05	$78.10
Licensed Practical Nurse/Licensed Vocational Nurse (LPN/LVN)	29-2061	$26.26	$26.26	$52.52

As described in Table XII.B–06, under OMB control number 0938–1163, we estimate that the policies finalized in this final rule for the LTCH QRP would result in an overall increase of 2,117 hours annually for 329 LTCHs. The total cost increase related to this proposed information collection is estimated at approximately $138,231.88. The increase in burden would be accounted for in a revised information collection request under OMB control number (0938–1163).

TABLE XII.B-06: ESTIMATED LTCH QRP PROGRAM IMPACTS FOR FY 2028

Proposal	Per LTCH		All LTCHs	
	Change in Annual Burden Hours	Change in Annual Cost	Change in Annual Burden Hours	Change in Annual Cost
Estimated change in burden associated with Proposal to Collect Four New Items As Standardized Patient Assessment Data Elements and Modify One Item Collected as a Standardized Patient Assessment Data Element beginning with the FY 2028 LTCH QRP	+6.43 hours	+$420.16	+2,117 hours	+$138,231.88

In section IX.E.7.c. of the preamble of this proposed rule, we are proposing to extend the LCDS Admission assessment window from three days to four days beginning with the FY 2028 LTCH QRP. However, this change would have no impact on burden.

We invite public comments on the proposed information collection requirements.

9. ICRs for the Medicare Promoting Interoperability Program

a. Background

In section IX.F. of the preamble of this proposed rule, we discuss several proposed policies for the Medicare

Promoting Interoperability Program. As discussed in the most recent Paperwork Reduction Act (PRA) notice pending approval under OMB control number 0938–1278 (expiration date December 31, 2025), we have requested approval for 29,625 hours of burden at a cost of approximately $1.3 million, accounting for information collection burden experienced by approximately 3,150 eligible hospitals and 1,350 CAHs for the EHR reporting period in CY 2024. In this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1278 for eligible hospitals and CAHs. The collection of information burden analysis in this proposed rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and report the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2025 through CY 2027.

We are proposing to adopt two new eCQMs beginning with the CY 2026 reporting period: (1) the Hospital Harm—Falls with Injury eCQM, and (2) the Hospital Harm—Postoperative Respiratory Failure eCQM. We are proposing to separate the previously finalized Antimicrobial Use and Resistance (AUR) Surveillance measure into two separate measures, beginning with the EHR reporting period in CY 2025: (1) the Antimicrobial Use (AU) Surveillance measure and (2) the Antimicrobial Resistance (AR) Surveillance Measure. We are also proposing to modify the Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period. In addition, we are proposing to increase the total number of eCQMs eligible hospitals and CAHs report from six to nine for the CY 2026 reporting period, and then from nine to eleven beginning with the CY 2027 reporting period. Lastly, we are proposing to increase the minimum scoring threshold from 60 points to 80 points beginning with the EHR reporting period in CY 2025; this proposal would not affect the information collection burden associated with the Medicare Promoting Interoperability Program.

In the FY 2024 IPPS/LTCH PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the BLS, to calculate our burden estimates for the Medicare Promoting Interoperability Program (88 FR 59325). Using the most recent data, the May 2022 National Occupational Employment and Wage Estimates (OEWS) from the BLS reflects a mean hourly wage of $24.56 per hour for all medical records specialists (SOC 29–2072), however, we are proposing to use the mean hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $26.06.[852] We believe the industry of ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to eligible hospitals and CAHs using a wage plus benefits estimate of $52.12 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59325), our burden estimates were based on an assumption of 4,500 eligible hospitals and CAHs. In the FY 2024 IPPS/LTCH PPS final rule, the Medicare Promoting Interoperability Program and Hospital IQR Program used the same estimate for the number of eligible hospitals and IPPS hospitals for both programs (88 FR 59325). In section XII.B.6.a. of the preamble of this proposed rule, we provide our updated estimate of 3,050 IPPS hospitals for the Hospital IQR Program for the CY 2025 reporting period. Upon further analysis, we believe it is no longer appropriate to use the same estimate for both programs as the approximately 100 eligible hospitals located in Maryland and Puerto Rico which were previously excluded from our estimate of IPPS hospitals and included in our estimate of non-IPPS hospitals should be included as eligible hospitals for the Medicare Promoting Interoperability Program. Therefore, for this proposed rule, based on data from the EHR reporting period in CY 2022, we estimate approximately 3,150 eligible hospitals and 1,400 CAHs will report data to the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025, for a total number of 4,550 respondents.

[852] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on January 3, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

b. Information Collection Burden for the Proposed Adoption of the Two eCQMs and Modification of One eCQM Beginning With the CY 2026 Reporting Period

In section IX.F.6.a. of the preamble of this proposed rule, we are proposing to adopt two new eCQMs beginning with the CY 2026 reporting period: (1) the Hospital Harm—Falls With Injury eCQM and (2) the Hospital Harm—Postoperative Respiratory Failure eCQM, to add to the set of eCQMs from which hospitals may self-select to meet their eCQM reporting requirements. In section IX.F.6.a. of the preamble of this proposed rule, we are proposing to modify the GMCS eCQM to add patients ages 18 to 64 to the current cohort of patients 65 years or older beginning with the CY 2026 reporting period.

Under OMB control number 0938–1278 (expiration date December 31, 2025), the currently approved burden estimate for reporting and submission of eCQM measures is one hour per CAH for all six required eCQM measures. The addition of these two eCQMs and modification of the GMCS eCQM do not affect the information collection burden associated with submitting eCQM measure data under the Medicare Promoting Interoperability Program. As finalized in the FY 2023 IPPS/LTCH PPS final rule, current policy requires CAHs to select six eCQMs from the eCQM measure set on which to report (87 FR 49365 through 49367). In other words, although these new eCQMs are being added to the eCQM measure set, CAHs are not required to report more than a total of six eCQMs.

In section XII.B.9.c. (of the Collection of Information section of this proposed rule), we account for the burden associated with our proposal to increase the total number of eCQMs reported from six to nine for the CY 2026 reporting period and then from nine to eleven beginning with the CY 2027 reporting period. We refer readers to section XII.B.7.f. of this Collection of Information section for discussion of the similar proposals impacting eligible hospitals (referred to as IPPS hospitals under the Hospital IQR Program).

c. Information Collection Burden for the Modification of the eCQM Reporting and Submission Requirements Beginning With the CY 2026 Reporting Period

In section IX.F.6.b. of the preamble of this proposed rule, we are proposing to modify our eCQM reporting and submission requirements by increasing

the total number of eCQMs to be reported from six to nine eCQMs for the CY 2026 reporting period and from nine to eleven beginning with the CY 2027 reporting period.

We previously finalized in the FY 2023 IPPS/LTCH PPS final rule that, for the CY 2024 reporting period, CAHs are required to annually submit quarterly data for six eCQMs each year, which must consist of the Safe Use of Opioids-Concurrent Prescribing, Cesarean Birth, and Severe Obstetric Complications eCQMs in addition to three self-selected eCQMs (87 FR 49394 through 49395). In this proposed rule, we are proposing that, for the CY 2026 reporting period, CAHs would be required to submit data for nine total eCQMs: three self-selected, Safe Use of Opioids, Severe Obstetric Complications, Cesarean Birth Rate, Hospital Harm—Severe Hypoglycemia, Hospital Harm—Severe Hyperglycemia, and Hospital Harm—Opioid-Related Adverse Events. We are also proposing that, beginning with the CY 2027 reporting period, CAHs would be required to submit data for these nine eCQMs as well as the Hospital Harm—Pressure Injury and Hospital Harm—Acute Kidney Injury eCQMs.

To calculate the information collection burden associated with this proposal, we estimate a total of 1,500 respondents, which includes the 100 eligible hospitals not included as IPPS hospitals for the Hospital IQR Program as well as the 1,400 CAHs required to report eCQM data for the Medicare Promoting Interoperability Program. We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. For the increase in submission from six to nine eCQMs for the CY 2026 reporting period, we estimate a total of 30 minutes or 0.5 hour (10 minutes × 3 eCQMs) per CAH per quarter. We estimate a total burden increase of 3,000 hours (0.5 hour × 1,500 CAHs × 4 quarters) at a cost of $156,360 (3,000 hours × $52.12). For the additional increase in submission from nine to eleven eCQMs beginning with the CY 2027 reporting period, we estimate a total of 50 minutes or 0.83 hour (10 minutes × 5 eCQMs) per CAH per quarter. We estimate a total burden increase of 5,000 hours annually (0.83 hour × 1,500 CAHs × 4 quarters) at a cost of $260,600 (5,000 hours × $52.12).

With respect to any costs/burdens related to eligible hospitals (referred to as IPPS hospitals under the Hospital IQR Program), we refer readers to section XII.B.7.f. of the preamble of this proposed rule.

d. Information Collection Burden for the Proposal To Separate the AUR Surveillance Measure Into Two Measures Beginning With the EHR Reporting Period in CY 2025

In section IX.F.2. of the preamble of this proposed rule, we are proposing to modify the AUR Surveillance measure by separating the single measure into two measures: (1) AU Surveillance and (2) AR Surveillance, beginning with the EHR reporting period in CY 2025. In the CY 2023 IPPS/LTCH PPS final rule, we finalized a burden estimate of 0.5 minutes per eligible hospital and CAH to attest the AUR Surveillance measure (87 FR 49394). In association with this proposal, we estimate an annual increase in burden for each eligible hospital and CAH to attest to both measures of 0.5 minutes (.0083 hours). Therefore, we estimate a total increase in burden of 38 hours across all eligible hospitals and CAHs (.0083 hours × 4,550 eligible hospitals and CAHs) annually at a cost of $1,981 (38 hours × $52.12).

e. Information Collection Burden for the Proposed Increase to the Minimum Scoring Threshold From 60 Points to 80 Points Beginning With the EHR Reporting Period in CY 2025

In section IX.F.5. of the preamble of this proposed rule, we are proposing to increase the minimum scoring threshold from 60 points to 80 points beginning with the EHR reporting period in CY 2025. Because we are not requiring eligible hospitals or CAHs to collect or submit any additional data, we do not estimate any change in information collection burden associated with this proposal.

f. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date December 31, 2025), we estimate that the policies in this proposed rule would result in an increase in burden of 5,038 hours at a cost of $262,581. Based on these proposed policies, the annual burden per eligible hospital and CAH would increase to 6 hours and 36 minutes (6.6 hours) as well as an additional 7.33 hours annually for CAHs to report eCQMs. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1278.

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.N. of Appendix A of this proposed rule).

TABLE XII.B-07: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE REPORTING PERIOD IN CY 2025

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the Reporting Period in CY 2025								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per hospital	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Modification to the AUR Surveillance Measure	0.5	1	4,550	1	0.0083	38	N/A	+38
	Total Change in Information Collection Burden Hours: +38							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+38) = **$1,981**							

TABLE XII.B-08: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE REPORTING PERIOD IN CY 2026

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the Reporting Period in CY 2026								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Modification to the AUR Surveillance Measure	0.5	1	4,550	1	0.0083	38	N/A	38
Adopt Modification to eCQM Reporting	90	4	1,500	9	1.5	9,000	6,000	+3,000
	Total Change in Information Collection Burden Hours: +3,038							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+3,038) = **$158,341**							

TABLE XII.B-09: SUMMARY OF MEDICARE PROMOTING INTEROPERABILITY PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE REPORTING PERIOD IN CY 2027

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1278 for the Reporting Period in CY 2027								
Activity	Estimated Time per Record (minutes)	Number Reporting Quarters per Year	Number of Respondents Reporting	Average Number Records per Respondent per quarter	Annual Burden (hours) per Respondent	Proposed Annual burden (hours) Across Hospitals	Previously Finalized Annual Burden (hours) across hospitals	Net Difference in Annual Burden Hours
Adopt Modification to the AUR Surveillance Measure	0.5	1	4,550	1	0.0083	38	N/A	+38
Adopt Modification to eCQM Reporting	110	4	1,500	11	1.83	11,000	6,000	+5,000
	Total Change in Information Collection Burden Hours: +5,038							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (+5,038) = **$262,581**							

10. ICRs for the Transforming Episode Accountability Model

In section X.A. of the preamble of this proposed rule, we are proposing to test the Transforming Episode Accountability Model (TEAM) under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

11. ICRs for Payment Error Rate Measurement (PERM)

a. ICRs Regarding § 431.970 Information Submission and Systems Access Requirements

Section 431.970 defines state and provider submission responsibilities, including state submission of Medicaid and CHIP FFS claims and managed care payments on a quarterly basis; and provider submission of medical records. These claims and payments are rigorously reviewed by the federal statistical contractor. Additionally, states are required to collect and submit (with an estimate of 4 submissions) state policies. There would be an initial submission and quarterly updates. The ongoing burden associated with the requirements under § 431.970 is the time and effort it would take each of the up to 36 state programs (17–18 Medicaid and 17–18 CHIP agencies for 17–18 states equates to maximum 36 total respondents each PERM year) to submit its claims universe, and collect and submit state policies, and the time and effort it would take providers to furnish medical record documentation. We estimate that it will take 1,350 hours annually per state program to develop and submit its claims universe and state policies. The total estimated hours is broken down between the FFS, managed care, and eligibility components and is estimated at 900 hours for universe development and submission, and 450 hours for policy collection and submission. Per component it is estimated at 1,150 FFS hours, 100 managed care hours, and 100 eligibility hours for a total of 48,600 annual hours (1,350 hours × 36 respondents). The total estimated annual cost per respondent is $86,832 (1,350 hours × $64.32), and the total estimated annual cost across all respondents is $3,125,952 ($86,832 × 36 respondents). The preceding requirements and burden estimates will be submitted to OMB as reinstatements with changes of the information collection requests previously approved under control numbers 0938–0974, 0938–0994, and 0938–1012. Inclusion of Puerto Rico has added an additional burden of 2,700 hours and $173,664 for Information Submission and Systems Access Requirements.

b. ICRs Regarding § 431.992 Corrective Action Plan

Section 431.992 requires states to submit corrective action plans to address all improper payments and deficiencies found through the PERM review as defined at § 431.960(f)(1) and evaluate corrective actions from the previous PERM cycle as defined at § 431.992(b)(4). The ongoing burden associated with the requirements under § 431.992 is the time and effort it would take each of the up to 36 state programs (17–18 Medicaid and 17–18 CHIP agencies for 17–18 states equates to maximum 36 total respondents per PERM cycle) to submit its corrective action plan. We estimate that it will take 750 hours (250 hours for FFS, 250 hours for managed care and an additional 250 hours for eligibility), per PERM cycle per state program to submit its corrective action plan for a total estimated annual burden of 27,000 hours (750 hours × 36 respondents). We estimate the total cost per respondent to be $48,240 (750 hours × $64.32). The

total estimated cost for all respondents is $1,736,640 ($48,240 × 36 respondents). The preceding requirements and burden estimates will be submitted to OMB as part of reinstatement of the information collection requests previously approved under control numbers 0938–0974, 0938–0994, and 0938–1012. total burden would amount to: 36 annual respondents, 36 annual responses, and 750 hours per corrective action plan Inclusion of Puerto Rico has added an additional burden of 1,500 hours and $96,480 for Corrective Action Plan requirements.

c. ICRs Regarding § 431.998 Difference Resolution and Appeal Process

Section 431.998 allows states to dispute federal contractor findings. The ongoing burden associated with the requirements under § 431.998 is the time and effort it would take each of the up to 36 state programs (17–18 Medicaid and 17–18 CHIP agencies for 17–18 states equates to maximum 36 total respondents per PERM cycle) to review PERM findings and inform the federal contractor(s) of any additional information and/or dispute requests. We estimate that it will take 1,625 hours (500 hours for FFS, 475 hours for managed care and an additional 650 hours for eligibility) per PERM cycle per state program to review PERM findings and inform federal contractor(s) of any additional information or dispute requests for FFS, managed care, and eligibility components for a total estimated annual burden of 58,500 hours (1,625 hours × 36 respondents). We estimate the total cost per respondent to be $104,520 (1,625 hours × $64.32). The total estimated cost for all respondents is $3,762,720 ($104,520 × 36 respondents). The preceding requirements and burden estimates will be submitted to OMB as reinstatements of the information collection requests previously approved under control numbers 0938–0974, 0938–0994, and 0938–1012. total burden would amount to: 36 annual respondents, 36 annual responses, and 1,625 hours per PERM cycle.

Inclusion of Puerto Rico has added an additional burden of 3,250 hours and $209,040 for Difference Resolution and Appeal Process requirements.

12. ICRs for the CoP Requirements for Hospitals and CAHs To Report Acute Respiratory Illnesses

a. Ongoing Reporting

The hospital must electronically report information on acute respiratory illnesses, including influenza, SARS–CoV–2/COVID–19, and RSV, in a standardized format and frequency specified by the Secretary. To the extent as required by the Secretary, this report must include the following data elements:

- Confirmed infections for a limited set of respiratory illnesses, including but not limited to influenza, SARS–CoV–2/COVID–19, and RSV, among newly admitted and hospitalized patients.
- Total bed census and capacity, including for critical hospital units and age groups.
- Limited patient demographic information, including but not limited to age.

For purposes of burden estimates, we do not differentiate among hospitals and CAHs as they all would collect data. For the estimated costs contained in the analysis that follows, we used data from the BLS to determine the mean hourly wage for the staff member responsible for reporting the required information for a hospital (or a CAH).[1] Based on our experience with hospitals and CAHs and the previous COVID–19 and related reporting requirements, we believe that this would primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $39.05. For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. Therefore, we estimated the total hourly cost for a registered nurse to perform these duties would be $78.

Based on the assumption of weekly reporting frequency, we estimate that total annual burden hours for all participating hospitals and CAHs to comply with these requirements would be 248,976 hours based on weekly reporting of the required information by approximately 6,384 hospitals and CAHs × 52 weeks per year and at an average weekly response time of 0.75 hours for a registered nurse with an average hourly salary of $78. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $19,420,128 (248,976 hours × 6,384 facilities) or approximately $3,042 per facility annually ($19,420,128/6,384 facilities).

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all hospitals and CAHs would report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. Our preliminary estimates for these reporting activities (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs) can be found in the tables that follow.

ESTIMATED ANNUALIZED BURDEN HOURS					
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent (low range - high range)	Average Burden per Response (in hours)	Total Burden Hours (low range – high range)
Hospitals and CAHs	Standardized format as determined by the Secretary	6,384	52	0.75	248,976
Total					248,976

ESTIMATED ANNUALIZED RESPONDENT BURDEN COSTS			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Hospitals and CAH Staff – Registered Nurses	248,976	*$78	$19,420,128
Total			$19,420,128

b. PHE Reporting

In the event that the Secretary has declared a national Public Health Emergency (PHE) for an acute respiratory illness or determined that a significant threat for one exists, the hospital must also electronically the report the following data elements in a standardized format and frequency specified by the Secretary:

- Supply inventory shortages.
- Staffing shortages.
- Relevant medical countermeasures and therapeutic inventories, usage, or both.
- Facility structure and operating status, including hospital/ED diversion status.

In addition, we propose reporting requirements for future acute respiratory illness PHEs or significant threats thereof that would require hospitals and CAHs to electronically report additional information on acute respiratory illnesses and related impacts on facility operations only when the Secretary has declared a national PHE directly related to such illnesses or determined that a significant threat for one exists. Specifically, we proposed that when the Secretary has declared an applicable PHE or identified a threat thereof, hospitals and CAHs would be required to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary.

For purposes of burden estimates, we do not differentiate among hospitals and CAHs as they all would complete the same data collection. For the estimated costs contained in the analysis that follows, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the staff member responsible for reporting the required information for a hospital (or a CAH).[2] Based on our experience with hospitals and CAHs and the previous COVID–19 and related reporting requirements, we believe that this would primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of $39.05. For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. Therefore, we estimated the total hourly cost for a registered nurse to perform these duties would be $78.

We acknowledge that the data elements and reporting frequency could increase or decrease due to the what the Secretary deems necessary for the given PHE; the changes would impact this burden estimate. For instance, data reporting requirements may be active for less than or more than a year. During the COVID–19 PHE, facilities reported daily. However, we cannot predict how often the Secretary would require data reporting for future PHE. Therefore, we included two burden estimates to encapsule a range in frequency of reporting. The lower range is based on twice a week reporting. The higher range is based on daily reporting.

Based on the assumption of twice weekly reporting frequency, we estimated that total annual burden hours for all participating hospitals and CAHs to comply with these requirements would be 995,904 hours based on twice weekly reporting of the required information by approximately 6,384 hospitals and CAHs × 104 days a year and at an average twice weekly response time of 1.5 hours for a registered nurse with an average hourly salary of $78. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $77,680,512 (995,904 hours × $78) or approximately $12,168 ($77,680,512/6,384 facilities) per facility annually.

Based on the assumption of daily reporting frequency, we estimated that total annual burden hours for all participating hospitals and CAHs to comply with these requirements would be 3,495,240 hours based on daily reporting of the required information by approximately 6,384 hospitals and CAHs × 365 days a year and at an average daily response time of 1.5 hours for a registered nurse with an average hourly salary of $78. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be $272,628,720 (3,495,240 hours × $78) or approximately $42,705 ($272,628,720/6,384 facilities) per facility annually.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all hospitals and CAHs would report manually. Efforts are underway to automate hospital and CAH reporting that have the potential to significantly decrease reporting burden and improve reliability. Our preliminary estimates for these reporting activities (OMB control numbers 0938–0328 for hospitals and 0938–1043 for CAHs) can be found in the tables that follow.

ESTIMATED ANNUALIZED BURDEN HOURS					
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent (low range -high range)	Average Burden per Response (in hours)	Total Burden Hours (low range – high range)
Hospitals and CAHs	Standardized format as determined by the Secretary	6,384	104 to 365	1.5	995,904 to 3,495,240
Total					

ESTIMATED ANNUALIZED RESPONDENT BURDEN COSTS			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Hospitals and CAH Staff – Registered Nurses	995,904 to 3,495,240	*$78	$ 77,680,512 to $ 272,628,720
Total			

XIII. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 2, 2024.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Incorporation by Reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1845 is amended by—

■ a. Revising paragraphs (a) and (b); and

■ b. Revising the paragraph (c) paragraph heading.

The revisions read as follows:

§ 405.1845 Composition of Board; hearings, decisions, and remands.

(a) *Composition of the Board.* The Board consists of five members appointed by the Secretary.

(1) All members must be knowledgeable in the field of payment of providers under Medicare Part A.

(2) At least one member must be a certified public accountant.

(3) At least two Board members must be representative of providers of services.

(b) *Terms of office.* The term of office for Board members must be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office.

(1) No member may serve more than three consecutive terms of office, except a Board member who, in their second or third consecutive term, is designated as Chairperson, as described in paragraph (c) of this section, may serve a maximum of four consecutive terms, provided that the Member continues to serve as Chairperson once so designated.

(2) The Secretary has the authority to terminate a Board member's term of office for good cause.

(c) *Role of the Chairperson.* * * *

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 3. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 412.1 is amended by revising paragraph (a)(1)(iv) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators, and for the additional resource costs for small, independent hospitals to establish and maintain access to buffer stocks of essential medicines.

* * * * *

■ 5. Section 412.2 is amended by adding paragraph (f)(11) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(f) * * *

(11) A payment adjustment for small, independent hospitals for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines as specified in § 412.113.

* * * * *

■ 6. Section 412.23 is amended by revising paragraphs (e)(3)(i), (iii), and (iv) and revising and republish paragraph (e)(4) to read as follows:

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) * * *

(3) * * *

(i) Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section and paragraphs (e)(4)(iv) and (v) of this section as applicable, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

* * * * *

(iii) If a change in a hospital's average length of stay specified under paragraph (e)(2)(i) or (e)(2)(ii) of this section would result in the hospital not maintaining an average Medicare inpatient length of stay of greater than 25 days, the calculation is made by the same method for the period of at least 5 months of the immediately preceding 6-month period.

(iv) [Reserved]

* * * * *

(4) For the purpose of calculating the average length of stay for hospitals

seeking to become long-term care hospitals, with the exception of paragraphs (e)(3)(iii) and (v) of this section, the provisions of paragraph (e)(3) of this section apply.

(i) *Definition.* For the purpose of payment under the long-term care hospital prospective payment system under subpart O of this part, a new long-term care hospital is a provider of inpatient hospital services that meets the qualifying criteria in paragraphs (e)(1) and (e)(2) of this section; meets the applicable requirements of paragraphs (e)(4)(ii) through (v) of this section; and, under present or previous ownership (or both), its first cost reporting period as a LTCH begins on or after October 1, 2002.

(ii) *Satellite facilities and remote locations of hospitals seeking to become new long-term care hospitals.* Except as specified in paragraph (e)(4)(iii) of this section, a satellite facility (as defined in § 412.22(h)) or a remote location of a hospital (as defined in § 413.65(a)(2) of this chapter) that voluntarily reorganizes as a separate Medicare participating hospital, with or without a concurrent change in ownership, and that seeks to qualify as a new long-term care hospital for Medicare payment purposes must demonstrate through documentation that it meets the average length of stay requirement as specified under paragraphs (e)(2)(i) or (e)(2)(ii) of this section based on discharges that occur on or after the effective date of its participation under Medicare as a separate hospital.

(iii) *Provider-based facility or organization identified as a satellite facility and remote location of a hospital prior to July 1, 2003.* Satellite facilities and remote locations of hospitals that became subject to the provider-based status rules under § 413.65 as of July 1, 2003, that become separately participating hospitals, and that seek to qualify as long-term care hospitals for Medicare payment purposes may submit to the fiscal intermediary discharge data gathered during 5 months of the immediate 6 months preceding the facility's separation from the main hospital for calculation of the average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section.

(iv) *Qualifying period for hospitals seeking to become long-term care hospitals.* A hospital may be classified as a long-term care hospital after a 6-month qualifying period, provided that the average length of stay during at least 5 consecutive months of that 6-month qualifying period, calculated under paragraph (e)(2) of this section, is greater than 25 days. The 6-month qualifying period for a hospital is the 6 months immediately preceding the date of long-term care hospital classification.

(v) *Special rule for hospitals seeking to become long-term care hospitals that experience a change in ownership.* If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in § 489.18 of this chapter) occurs within the period of at least 5 months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

* * * * *

■ 7. Section 412.88 is amended by adding paragraphs (a)(2)(ii)(C) and (b)(2)(iv) to read as follows:

§ 412.88 Additional payment for new medical service or technology.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(C) For a medical product that is a gene therapy that is indicated and used specifically for the treatment of sickle cell disease and approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule, for discharges occurring on or after October 1, 2024, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(*1*) 75 percent of the costs of the new medical service or technology; or

(*2*) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

* * * * *

(b) * * *

(2) * * *

(iv) For discharges occurring on or after October 1, 2024, for a medical product that is a gene therapy that is indicated and used specifically for the treatment of sickle cell disease and approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule, 75 percent of the estimated costs of the new medical service or technology.

■ 8. Section 412.90 is amended by revising paragraph (j) to read as follows:

§ 412.90 General rules.

* * * * *

(j) Medicare-dependent, small rural hospitals. For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before January 1, 2025, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

* * * * *

■ 9. Section 412.96 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(c) * * *

(2) * * *

(ii) For cost reporting periods beginning on or after January 1, 1986, an osteopathic hospital, recognized by the American Osteopathic Healthcare Association (or any successor organization), that is located in a rural area must have at least 3,000 discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section to meet the number of discharges criterion. A hospital applying for rural referral center status under the number of discharges criterion in this paragraph must demonstrate its status as an osteopathic hospital.

* * * * *

■ 10. Section 412.101 is amended by revising paragraphs (b)(2)(i), (b)(2)(iii), (c)(1), and (c)(3) introductory text to read as follows:

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

* * * * *

(b) * * *

(2) * * *

(i) For FY 2005 through FY 2010, the portion of FY 2025 beginning on January 1, 2025 and subsequent fiscal years, a hospital must have fewer than 200 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 25 road miles (as defined in paragraph (a) of this

section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

* * * * *

(iii) For FY 2019 through FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024, a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

* * * * *

(c) * * *

(1) For FY 2005 through FY 2010, the portion of FY 2025 beginning on January 1, 2025 and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

* * * * *

(3) For FY 2019 through FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024, the adjustment is as follows:

* * * * *

■ 11. Section 412.103 is amended by revising paragraph (a)(1) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) * * *

(1) The hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, using the Rural-Urban Commuting Area codes and additional criteria, as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA), which is available at the web link provided in the most recent **Federal Register** notice issued by HRSA defining rural areas.

* * * * *

■ 12. Section 412.104 is amended by revising paragraphs (b)(2) through (b)(4) to read as follows:

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

* * * * *

(b) * * *

(2)(i) Effective for cost reporting periods beginning before October 1, 2024, the estimated weekly cost of dialysis is the average number of dialysis sessions furnished per week during the 12-month period that ended June 30, 1983, multiplied by the average cost of dialysis for the same period.

(ii) Effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis is calculated as 3 dialysis sessions per week multiplied by the applicable ESRD prospective payment system (PPS) base rate (as defined in 42 CFR 413.171) that corresponds with the fiscal year in which the cost reporting period begins.

(3) The average cost of dialysis used for purposes of determining the estimated weekly cost of dialysis for cost reporting periods beginning before October 1, 2024, includes only those costs determined to be directly related to the renal dialysis services. (These costs include salary, employee health and welfare, drugs, supplies, and laboratory services.)

(4) Effective for cost reporting periods beginning before October 1, 2024, the average cost of dialysis is reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed.

* * * * *

■ 13. Section 412.105 is amended by adding paragraph (f)(1)(iv)(C)(*4*) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(C) * * *

(*4*) Effective for portions of cost reporting periods beginning on or after July 1, 2026, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in § 413.79(q) of this subchapter are met.

* * * * *

■ 14. Section 412.106 is amended by revising paragraph (i)(1) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(i) * * *

(1) Interim payments are made during the payment year to each hospital that is estimated to be eligible for payments under this section at the time of the annual final rule for the hospital inpatient prospective payment system, subject to the final determination of eligibility at the time of cost report settlement for each hospital. For FY 2025 and subsequent fiscal years, interim uncompensated care payments are calculated based on an average of the most recent 3 years of available historical discharge data.

* * * * *

■ 15. Section 412.108 is amended by revising paragraphs (a)(1) introductory text and (c)(2)(iii) introductory text to read as follows:

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) * * *

(1) *General considerations.* For cost reporting periods beginning on or after April 1, 1990, and ending before October 1, 1994, or for discharges occurring on or after October 1, 1997, and before January 1, 2025, a hospital is classified as a Medicare-dependent, small rural hospital if it meets all of the following conditions:

* * * * *

(c) * * *

(2) * * *

(iii) For discharges occurring during cost reporting periods (or portions thereof) beginning on or after October 1, 2006, and before January 1, 2025, 75 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the highest of the following:

* * * * *

■ 16. Section 412.113 is amended by adding paragraph (g) to read as follows:

§ 412.113 Other payments.

* * * * *

(g) *Additional resource costs of establishing and maintaining access to buffer stocks of essential medicines.* (1) Essential medicines are the 86 medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022, and any subsequent revisions to that list of medicines. A buffer stock of essential medicines for a hospital is a supply, for no less than a 6-month period of one or more essential medicines.

(2) The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients or arrange contractually for such a buffer stock to be held by another entity for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves.

(3) For cost reporting periods beginning on or after October 1, 2024, a payment adjustment to a small, independent hospital for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines is made as described in paragraph (g)(4) of this section. For purposes of this section, a small, independent hospital is a hospital with 100 or fewer beds as defined in § 412.105(b) during the cost reporting period that is not part of a chain organization, defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.

(4) The payment adjustment is based on the estimated reasonable cost incurred by the hospital for establishing and maintaining access to buffer stocks of essential medicines during the cost reporting period.

■ 17. Section 412.140 is amended by revising paragraphs (d)(2)(ii) and (e)(2)(vii) introductory text to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(d) * * *

(2) * * *

(ii)(A) Prior to the FY 2028 payment determination, a hospital meets the eCQM validation requirement with respect to a fiscal year if it submits 100 percent of sampled eCQM measure medical records in a timely and complete manner, as determined by CMS.

(B) For the FY 2028 payment determination and later years, a hospital meets the eCQM validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

* * * * *

(e) * * *

(2) * * *

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain a detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

* * * * *

§ 412.230 [Amended]

■ 18. In § 412.230 amend paragraph (a)(5)(i) by removing the phrase ''in the rural area of the state'' and adding in its place the phrase ''either in its geographic area or in the rural area of the State''.

■ 19. Amend § 412.273 by revising paragraphs (c)(1)(ii) and (c)(2) to read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

* * * * *

(c) * * *

(ii) After the MGCRB issues a decision, provided that the request for withdrawal is received by the MCGRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.278, whichever is later concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed.

(2) A request for termination must be received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.278, whichever is later concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the termination is to apply.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 20. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

§ 413.75 [Amended]

■ 21. Section 413.75 is amended in paragraph (b), in the definition of ''Emergency Medicare GME Affiliated Group'' by removing the reference ''§ 413.79(f)(6)'' and adding in its place the reference ''§ 413.79(f)(7)''.

§ 413.78 [Amended]

■ 22. Section 413.78 is amended by—

■ a. In paragraph (e)(3)(iii), removing the reference ''§ 413.79(f)(6)'' and adding in its place the reference ''§ 413.79(f)(7)''; and

■ b. In paragraph (f)(3)(iii) introductory text, removing the reference ''§ 413.79(f)(6)'' and adding in its place the reference ''§ 413.79(f)(7)''.

■ 23. Section 413.79 is amended by—

■ a. Revising paragraphs (d)(6), (f)(8) and (k)(2)(i); and

■ b. Adding paragraph (q).

The revisions and addition read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(d) * * *

(6) Subject to the provisions of paragraph (h) of this section, FTE residents who are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the averaging rules in this paragraph (d), for the receiving hospital for the duration of the time that the displaced residents are training at the receiving hospital.

* * * * *

(f) * * *

(8) FTE resident cap slots added under section 126 of Public Law 116–260 and section 4122 of Public Law 117–328 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

* * * * *

(k) * * *

(2) * * *

(i)(A) For rural track programs started before October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(B) For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(C) For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural

hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital and subject to the requirements under § 413.78(g), at the rural nonprovider site(s).

* * * * *

(q) *Determination of an increase in the otherwise applicable resident cap under section 4122 of the Consolidated Appropriations Act (Pub. L. 117—328).* For portions of cost reporting periods beginning on or after July 1, 2026, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(10) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 24. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

§ 431.954 [Amended]

■ 25. Section 431.954 is amended in paragraph (b)(3) by removing the phrase ''Puerto Rico, Guam,'' and adding in its place the word ''Guam,''.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 26. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 27. Section 482.42 is amended by revising paragraph (e) and removing paragraph (f) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *Respiratory illness reporting*—(1) *Ongoing reporting.* The hospital must electronically report information on acute respiratory illnesses, including influenza, SARS–CoV–2/COVID–19, and RSV.

(i) The report must be in a standardized format and frequency specified by the Secretary.

(ii) To the extent as required by the Secretary, this report must include all of the following data elements:

(A) Confirmed infections for a limited set of respiratory illnesses, including but not limited to influenza, SARS–CoV–2/COVID–19, and RSV, among newly admitted and hospitalized patients.

(B) Total bed census and capacity, including for critical hospital units and age groups.

(C) Limited patient demographic information, including but not limited to age.

(2) *Public health emergency (PHE) reporting.* In the event that the Secretary has declared a national, state, or local PHE for an acute infectious illness or determined that a significant threat for one exists, the hospital must also electronically the report the following data elements in a standardized format and frequency specified by the Secretary:

(i) Supply inventory shortages.

(ii) Staffing shortages.

(iii) Relevant medical countermeasures and therapeutic inventories, usage, or both.

(iv) Facility structure and operating status, including hospital/ED diversion status.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 28 The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 29. Section 485.640 is amended revising paragraph (d) and removing paragraph (e) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *Respiratory illness reporting*—(1) *Ongoing reporting.* The CAH must electronically report information on acute respiratory illnesses, including influenza, SARS–CoV–2/COVID–19, and RSV.

(i) The report must be in a standardized format and frequency specified by the Secretary.

(ii) To the extent as required by the Secretary, the report must include the following data elements:

(A) Confirmed infections for a limited set of respiratory illnesses, including but not limited to influenza, SARS–CoV–2/COVID–19, and RSV, among newly admitted and hospitalized patients.

(B) Total bed census and capacity, including for critical hospital units and age groups.

(C) Limited patient demographic information, including but not limited to age.

(2) *Public health emergency (PHE) reporting.* In the event that the Secretary has declared a national, state, or local PHE for an acute infectious illness or determined that a significant threat for one exists, the CAH must also electronically the report the following data elements in a standardized format and frequency specified by the Secretary:

(i) Supply inventory shortages.

(ii) Staffing shortages.

(iii) Relevant medical countermeasures and therapeutic inventories, usage, or both.

(iv) Facility structure and operating status, including CAH/ED diversion status.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 30. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 31. Section 495.24 is amended by—

■ a. In paragraph (f)(1)(i)(B) removing the phrase ''In 2023 and subsequent years'' and adding in its place the phrase ''In 2023 and 2024,''; and

■ b. Adding paragraph (f)(1)(i)(C).

The addition reads as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(C) In 2025 and subsequent years, earn a total score of at least 80 points.

* * * * *

■ 32. Revise the heading for part 512 to read as follows:

PART 512—STANDARD PROVISIONS FOR INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 33. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 34. Amend part 512 by adding subparts D and E to read as follows:

Subpart D [Reserved]

Subpart E—Transforming Episode Accountability Model (TEAM)

Sec.

General

512.500 Basis and scope of subpart.
512.505 Definitions

TEAM Participation

512.515 Geographic areas.

General

§ 512.500 Basis and scope of subpart.

(a) *Basis.* This subpart implements the test of the Transforming Episode Accountability Model (TEAM) under section 1115A(b) of the Act. Except as specifically noted in this part, the regulations under this subpart do not affect the applicability of other provisions affecting providers and suppliers under Medicare FFS, including the applicability of provisions regarding payment, coverage, and program integrity.

(b) *Scope.* This subpart sets forth the following:

(i) Participation in TEAM.

(ii) Scope of episodes being tested.

(iii) Pricing methodology.

(iv) Quality measures and quality reporting requirements.

(v) Reconciliation and review processes.

(vi) Data sharing and other requirements

(vii) Financial arrangements and beneficiary incentives.

(viii) Medicare program waivers

(ix) Beneficiary protections.

(x) Cooperation in model evaluation and monitoring.

(xi) Audits and record retention.

(xii) Rights in data and intellectual property.

(xiii) Monitoring and compliance.

(xiv) Remedial action.

(xv) Limitations on review.

(xvi) Miscellaneous provisions on bankruptcy and other notifications.

(xvii) Model termination by CMS.

(xviii) Decarbonization.

§ 512.505 Definitions

For the purposes of this part, the following definitions are applicable unless otherwise stated:

AAPM stands for Advanced Alternative Payment Model.

AAPM option means the advanced alternative payment model option of TEAM for Track 2 and Track 3 TEAM participants that provide their CMS EHR Certification ID and attest to their use of CEHRT in accordance with § 512.522.

ACO means an accountable care organization, as defined at § 425.20 of this chapter.

ACO participant has the meaning set forth in § 425.20 of this chapter.

ACO provider/supplier has the meaning set forth in § 425.20 of this chapter.

Acute care hospital means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Age bracket risk adjustment factor means the coefficient of risk associated with a patient's age bracket, calculated as described in § 512.545(a)(1).

Aggregated reconciliation target price refers to the sum of the reconciliation target prices for all episodes attributed to a given TEAM participant for a given performance year.

Alignment payment means a payment from a TEAM collaborator to a TEAM participant under a sharing arrangement, for the sole purpose of sharing the TEAM participant's responsibility for making repayments to Medicare.

Anchor hospitalization means the initial hospital stay upon admission for an episode category included in TEAM, as described in § 512.525(c), for which the institutional claim is billed through the inpatient prospective payment system (IPPS).

Anchor procedure means a procedure related to an episode category, as described in § 512.525(c), included in TEAM that is permitted and paid for by Medicare when performed in a hospital outpatient department (HOPD) and billed through the Hospital Outpatient Prospective Payment System (OPPS).

ADI stands for Area Deprivation Index.

APM stands for Alternative Payment Model.

APM Entity means an entity as defined in § 414.1305 of this chapter.

Baseline episode spending refers to total episode spending by all providers and suppliers associated with a given MS–DRG/HCPCS episode type for all hospitals in a given region during the baseline period.

Baseline period means the 3-year historical period used to construct the preliminary target price and reconciliation target price for a given performance year.

Baseline year means any one of the3 years included in the baseline period.

Benchmark price means average standardized episode spending by all providers and suppliers associated with a given MS–DRG/HCPCS episode type for all hospitals in a given region during the applicable baseline period.

Beneficiary means an individual who is enrolled in Medicare FFS.

BPCI stands for the Bundled Payments for Care Improvement Model, which was an episode-based payment initiative with four models tested by the CMS Innovation Center from April 2013 to September 2018.

BPCI Advanced stands for the Bundled Payments for Care Improvement Advanced Model, which is an episode-based payment model tested by the CMS Innovation Center from October 2018 to December 2025.

CCN stands for CMS certification number.

CEHRT means certified electronic health record technology that meets the requirements set forth in § 414.1305 of this chapter.

Change in control means any of the following:

(1) The acquisition by any ''person'' (as this term is used in sections 13(d)

and 14(d) of the Securities Exchange Act of 1934) of beneficial ownership (within the meaning of Rule 13d–3 promulgated under the Securities Exchange Act of 1934), directly or indirectly, of voting securities of the TEAM participant representing more than 50 percent of the TEAM participant's outstanding voting securities or rights to acquire such securities.

(2) The acquisition of the TEAM participant by any individual or entity.

(3) The sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the TEAM participant.

(4) The approval and completion of a plan of liquidation of the TEAM participant, or an agreement for the sale or liquidation of the TEAM participant.

CJR stands for the Comprehensive Care for Joint Replacement Model, which is an episode-based payment model tested by the CMS Innovation Center from April 2016 to December 2024.

Clinician engagement list means the list of eligible clinicians or MIPS eligible clinicians that participate in TEAM activities and have a contractual relationship with the TEAM participant, and who are not listed on the financial arrangements list, as described in § 512.522(c).

CMS Electronic Health Record (EHR) Certification ID means the identification number that represents the combination of Certified Health Information Technology that is owned and used by providers and hospitals to provide care to their patients and is generated by the Certified Health Information Technology Product List.

Collaboration agent means an individual or entity that is not a TEAM collaborator and that is either of the following:

(1) A member of a PGP, NPPGP, or TGP that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a TEAM collaborator.

(2) An ACO participant or ACO provider/supplier that has entered into a distribution arrangement with the same ACO in which it is participating, and where the ACO is a TEAM collaborator.

Composite quality score (CQS) means a score computed for each TEAM participant to summarize the TEAM participant's level of quality performance and improvement on specified quality measures as described in § 512.547.

Core-based statistical area (CBSA) means a statistical geographic entity defined by the Office of Management and Budget (OMB) consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

CORF stands for comprehensive outpatient rehabilitation facility.

Coronary artery bypass graft (CABG) means any coronary revascularization procedure paid through the IPPS under MS–DRG 231–236, including both elective CABG and CABG procedures performed during initial acute myocardial infarction treatment (AMI).

Covered services means the scope of health care benefits described in sections 1812 and 1832 of the Act for which payment is available under Part A or Part B of Title XVIII of the Act.

Critical access hospital (CAH) means a hospital designated under subpart F of part 485 of this chapter.

CQS adjustment amount means the amount subtracted from the positive or negative reconciliation amount to generate the reconciliation payment or repayment amount.

CQS adjustment percentage means the percentage CMS applies to the positive or negative reconciliation amount based on the TEAM participant's CQS performance.

CQS baseline period means calendar year 2025 and is the time period used to benchmark quality measure performance.

Days means calendar days.

Decarbonization and Resilience Initiative means an initiative for TEAM participants that includes technical assistance on decarbonization and a voluntary reporting program where TEAM participants may annually report metrics and questions related to emissions in accordance with § 512.598.

Descriptive TEAM materials and activities means general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, social media, or other materials or activities distributed or conducted by or on behalf of the TEAM participant or its downstream participants when used to educate, notify, or contact beneficiaries regarding TEAM. All of the following communications are not descriptive TEAM materials and activities:

(1) Communications that do not directly or indirectly reference TEAM (for example, information about care coordination generally).

(2) Information on specific medical conditions.

(3) Referrals for health care items and services, except as required by § 512.564.

(4) Any other materials that are excepted from the definition of ''marketing'' as that term is defined at 45 CFR 164.501.

Discount factor means a set percentage included in the preliminary target price and reconciliation target price intended to reflect Medicare's potential savings from TEAM.

Distribution arrangement means a financial arrangement between a TEAM collaborator that is an ACO, PGP, NPPGP, or TGP and a collaboration agent for the sole purpose of distributing some or all of a gainsharing payment received by the ACO, PGP, NPPGP, or TGP.

Distribution payment means a payment from a TEAM collaborator that is an ACO, PGP, NPPGP, or TGP to a collaboration agent, under a distribution arrangement, composed only of gainsharing payments.

DME stands for durable medical equipment.

Downstream collaboration agent means an individual who is not a TEAM collaborator or a collaboration agent and who is a member of a PGP, NPPGP, or TGP that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

Downstream distribution arrangement means a financial arrangement between a collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant and a downstream collaboration agent for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP.

Downstream participant means an individual or entity that has entered into a written arrangement with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent under which the downstream participant engages in one or more TEAM activities.

Dually eligible beneficiary means a beneficiary enrolled in both Medicare and full Medicaid benefits.

EHR stands for electronic health record.

Eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Episode category means one of the five episodes tested in TEAM as described at § 512.525(d).

Episode means all Medicare Part A and B items and services described in § 512.525(e) (and excluding the items and services described in § 512.525(f)) that are furnished to a beneficiary

described in § 512.535 during the time period that begins on the date of the beneficiary's admission to an anchor hospitalization or the date of the anchor procedure, as described at § 512.525(c), and ends on the 30th day following the date of discharge from the anchor hospitalization or anchor procedure, with the date of discharge or date of the anchor procedure itself being counted as the first day in the 30-day post-discharge period, as described at § 512.537. In the case that an anchor hospitalization for the same episode category occurs within 3 days of an anchor procedure, the anchor procedure episode is canceled, and the episode start date for the anchor hospitalization is the same as the outpatient procedure.

Essential access community hospital means a hospital as defined under § 412.109 of this chapter.

Final normalization factor refers to the national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type.

Financial arrangements list means the list of eligible clinicians or MIPS eligible clinicians that have a financial arrangement with the TEAM participant, TEAM collaborator, collaboration agent, and downstream collaboration agent, as described in § 512.522(b).

Gainsharing payment means a payment from a TEAM participant to a TEAM collaborator, under a sharing arrangement, composed of only reconciliation payments, internal cost savings, or both.

HCPCS stands for Healthcare Common Procedure Coding System, which is used to bill for items and services.

Health disparities means preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health, health quality, or health outcomes that are experienced by one or more underserved communities within the TEAM participant's population of TEAM beneficiaries that the participant will aim to reduce.

Health equity goal means a targeted outcome relative to health equity plan performance measures.

Health equity plan means a document that identifies health equity goals, intervention strategies, and performance measures to improve health disparities identified within the TEAM participant's population of TEAM beneficiaries that the TEAM participant will aim to reduce as described in § 512.563.

Health equity plan intervention strategy means the initiative the TEAM participant creates and implements to reduce the identified health disparities as part of the health equity plan.

Health equity plan performance measure means a quantitative metric that the TEAM participant uses to measure changes in health disparities arising from the health equity plan intervention strategies.

HHA means a Medicare-enrolled home health agency.

High-cost outlier cap refers to the 99th percentile of regional spending for a given MS–DRG/HCPCS episode type in a given region, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending.

Hospital means a hospital as defined in section 1886(d)(1)(B) of the Act.

Hospital discharge planning means the standards set forth in § 482.43 of this chapter.

ICD–CM stands for International Classification of Diseases, Clinical Modification.

Internal cost savings means the measurable, actual, and verifiable cost savings realized by the TEAM participant resulting from care redesign undertaken by the TEAM participant in connection with providing items and services to TEAM beneficiaries within an episode. Internal cost savings does not include savings realized by any individual or entity that is not the TEAM participant.

IPF stands for inpatient psychiatric facility.

IPPS stands for Inpatient Prospective Payment System, which is the payment system for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

IRF stands for inpatient rehabilitation facility.

LIS stands for Medicare Part D Low-Income Subsidy.

Lower-extremity joint replacement (LEJR) means any hip, knee, or ankle replacement that is paid under MS–DRG 469, 470, 521, or 522 through the IPPS or HCPCS code 27447, 27130, or 27702 through the OPPS.

LTCH stands for long-term care hospital.

Major bowel procedure means any small or large bowel procedure paid through the IPPS under MS–DRG 329–331.

Mandatory CBSA means a core-based statistical area selected by CMS in accordance with § 512.520 where all eligible hospitals are required to participate in TEAM.

MDC stands for Major Diagnostic Category.

Medically necessary means reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member.

Medicare severity diagnosis-related group (MS–DRG) means, for the purposes of this model, the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

Medicare-dependent, small rural hospital (MDH) means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

Member of the NPPGP or *NPPGP member* means a nonphysician practitioner or therapist who is an owner or employee of an NPPGP and who has reassigned to the NPPGP his or her right to receive Medicare payment.

Member of the PGP or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

Member of the TGP or *TGP member* means a therapist who is an owner or employee of a TGP and who has reassigned to the TGP his or her right to receive Medicare payment.

MIPS stands for Merit-based Incentive Payment System

MIPS eligible clinician means a clinician as defined in § 414.1305 of this chapter.

Model-specific payment means a payment made by CMS only to TEAM participants and includes, unless otherwise specified, the reconciliation payment.

Model performance period means the 60-month period from January 1, 2026, to December 31, 2030, during which TEAM is being tested and the TEAM participant is held accountable for spending and quality.

Model start date means January 1, 2026, the start of the model performance period.

MS–DRG/HCPCS episode type refers to the subset of episodes within an episode category that are associated with a given MS–DRG/HCPCS, as set forth at § 512.540(a)(1).

Non-AAPM option means the option of TEAM for TEAM participants in Track 1 or for TEAM participants in Track 2 or Track 3 that do not attest to use of CEHRT as described in § 512.522.

Nonphysician practitioner means one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b) of this chapter).

(5) A clinical social worker (as defined at § 410.73(a) of this chapter).

(6) A registered dietician or nutrition professional (as defined at § 410.134 of this chapter).

NPI stands for National Provider Identifier.

NPPGP stands for Non-Physician Provider Group Practice, which means an entity that is enrolled in Medicare as a group practice, includes at least one owner or employee who is a nonphysician practitioner, does not include a physician owner or employee, and has a valid and active TIN.

NPRA stands for Net Payment Reconciliation Amount, which means the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality and stop-gain/stop-loss limits, but prior to the post-episode spending adjustment.

OIG stands for the Department of Health and Human Services Office of the Inspector General.

OP means an outpatient procedure for which the institutional claim is billed by the hospital through the OPPS.

OPPS stands for the Outpatient Prospective Payment System.

PAC stands for post-acute care.

PBPM stands for per-beneficiary-per-month.

Performance year means a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period.

Performance year spending means the sum of standardized Medicare claims payments during the performance year for the items and services that are included in the episode in accordance with § 512.525(e), excluding the items and services described in § 512.525(f).

PGP stands for physician group practice.

Physician has the meaning set forth in section 1861(r) of the Act.

Post-episode spending amount means the sum of all Medicare Parts A and B payments for items and services furnished to a beneficiary within 30 days after the end of an episode and includes the prorated portion of services that began during the episode and extended into the 30-day post-episode period.

Preliminary target price refers to the target price provided to the TEAM participant prior to the start of the performance year, which is subject to adjustment at reconciliation, as set forth at § 512.540.

Primary care services has the meaning set forth in section 1842(i)(4) of the Act.

Prospective normalization factor refers to the multiplier incorporated into the preliminary target price to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price, calculated as set forth in § 512.540(b)(6).

Prospective trend factor refers to the multiplier incorporated into the preliminary target price to estimate changes in spending patterns between the baseline period and the performance year, calculated as set forth in § 512.540(b)(7).

Provider means a ''provider of services'' as defined under section 1861(u) of the Act and codified in the definition of ''provider'' at § 400.202 of this chapter.

Provider of outpatient therapy services means an entity that is enrolled in Medicare as a provider of therapy services and furnishes one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

QP stands for Qualifying APM Participant as defined in § 414.1305 of this chapter.

Quality-adjusted reconciliation amount refers to the dollar amount representing the difference between the reconciliation target price and performance year spending, after adjustments for quality, but prior to application of stop-gain/stop-loss limits and the post-episode spending adjustment.

Raw quality measure score means the quality measure value as obtained from the Hospital Inpatient Quality Reporting Program and the Hospital-Acquired Condition Reduction Program.

Reconciliation amount means the dollar amount representing the difference between the reconciliation target price and performance year spending, prior to adjustments for quality, stop-gain/stop-loss limits, and post-episode spending.

Reconciliation payment amount means the amount that CMS may owe to a TEAM participant after reconciliation as determined in accordance with § 512.550(g).

Reconciliation target price means the target price applied to an episode at reconciliation, as determined in accordance with § 512.545.

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

Reorganization event refers to a merger, consolidation, spin off or other restructuring that results in a new hospital entity under a given CCN.

Repayment amount means the amount that the TEAM participant may owe to Medicare after reconciliation as determined in accordance with § 512.550(g).

Rural hospital means an IPPS hospital that meets one of the following criteria:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

(4) Is a rural referral center (RRC), which has the same meaning given this term under § 412.96 of this chapter.

Safety Net hospital means an IPPS hospital that meets at least one of the following criteria:

(1) Exceeds the 75th percentile of the proportion of Medicare beneficiaries considered dually eligible for Medicare and Medicaid across all PPS acute care hospitals in the baseline period.

(2) Exceeds the 75th percentile of the proportion of Medicare beneficiaries partially or fully eligible to receive Part D low-income subsidies across all PPS acute care hospitals in the baseline period.

Scaled quality measure score means the score equal to the percentile to which the TEAM participant's raw quality measure score would have belonged in the CQS baseline period.

Sharing arrangement means a financial arrangement between a TEAM participant and a TEAM collaborator for the sole purpose of making gainsharing payments or alignment payments under TEAM.

SNF stands for skilled nursing facility.

Sole community hospital (SCH) means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

Spinal fusion means any cervical, thoracic, or lumbar spinal fusion procedure paid through the IPPS under MS–DRG 453–455, 459–460, or 471–473, or through the OPPS under HCPCS codes 22551, 22554, 22612, 22630, or 22633.

SHFFT (Surgical Hip and Femur Fracture Treatment) means a hip fixation procedure, with or without

fracture reduction, but excluding joint replacement, that is paid through the IPPS under MS–DRGs 480–482.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

TAA stands for total ankle arthroplasty.

TEAM activities mean any activity related to promoting accountability for the quality, cost, and overall care for TEAM beneficiaries and performance in the model, including managing and coordinating care; encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty under the model.

TEAM beneficiary means a beneficiary who meets the beneficiary inclusion criteria in § 512.535 and who is in an episode.

TEAM collaborator means an ACO or one of the following Medicare-enrolled individuals or entities that enters into a sharing arrangement:

(1) SNF.
(2) HHA.
(3) LTCH.
(4) IRF.
(5) Physician.
(6) Nonphysician practitioner.
(7) Therapist in private practice.
(8) CORF.
(9) Provider of outpatient therapy services.
(10) PGP.
(11) Hospital.
(12) CAH.
(13) NPPGP.
(14) Therapy Group Practice (TGP).

TEAM data sharing agreement means an agreement between the TEAM participant and CMS that includes the terms and conditions for any beneficiary-identifiable data shared with the TEAM participant under § 512.562.

TEAM HCC count refers to the TEAM Hierarchical Condition Category count, which is a categorical risk adjustment variable designed to reflect a beneficiary's overall health status during a 90-day lookback period by grouping similar diagnoses into one related category and counting the total number of diagnostic categories that apply to the beneficiary.

TEAM participant means an acute care hospital that initiates episodes and is paid under the IPPS with a CCN primary address located in one of the geographic areas selected for participation in TEAM in accordance with § 512.515.

TEAM payment means a payment made by CMS only to TEAM participants, or a payment adjustment made only to payments made to TEAM participants, under the terms of TEAM that is not applicable to any other providers or suppliers.

TEAM reconciliation report means the report prepared after each reconciliation that CMS provides to the TEAM participant notifying the TEAM participant of the outcome of the reconciliation.

TGP or therapy group practice means an entity that is enrolled in Medicare as a therapy group in private practice, includes at least one owner or employee who is a therapist in private practice, does not include an owner or employee who is a physician or nonphysician practitioner, and has a valid and active TIN.

THA means total hip arthroplasty.

Therapist means one of the following individuals as defined at § 484.4 of this chapter:

(1) Physical therapist.
(2) Occupational therapist.
(3) Speech-language pathologist.

Therapist in private practice means a therapist that—

(1) Complies with the special provisions for physical therapists in private practice in § 410.60(c) of this chapter;

(2) Complies with the special provisions for occupational therapists in private practice in § 410.59(c) of this chapter; or

(3) Complies with the special provisions for speech-language pathologists in private practice in § 410.62(c) of this chapter.

TIN stands for taxpayer identification number.

TKA stands for total knee arthroplasty.

Track 1 means a participation track in TEAM in which a TEAM participant may participate for the first performance year. TEAM participants in Track 1 are subject to the CQS adjustment percentage described in § 512.550(d)(1)(i), the limitations on gain described in § 512.550(e)(2) and the calculation of the reconciliation payment described in § 512.550(g).

Track 2 means a participation track in TEAM in which certain TEAM participants, as described in § 512.520(b)(3), may request to participate in for performance years 2 through 5. TEAM participants in Track 2 are subject to the CQS adjustment percentage described in § 512.550(d)(1)(ii), limitations on gain and loss described in § 512.550(e)(2) and § 512.550(e)(3), and the calculation of the reconciliation payment or repayment amount described in § 512.550(g).

Track 3 means a participation track in TEAM in which a TEAM participant may participate in for performance years 1 through 5. TEAM participants in Track 3 are subject to the CQS adjustment percentage described in § 512.550(d)(1)(iii), limitations on loss and gain described in § 512.550(e)(1) and in § 512.550(e)(2), and the calculation of the reconciliation payment or repayment amount described in § 512.550(g).

Underserved community means a population sharing a particular characteristic, including geography, that has been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.

U.S. Territories means American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

Weighted scaled score means the scaled quality measure score multiplied by its normalized weight.

TEAM Participation

§ 512.515 Geographic areas.

(a) *General.* CMS selects the CBSAs included in TEAM. All acute care hospitals paid under the IPPS and located within the selected CBSAs must participate in TEAM. CMS uses a stratified random sampling to select the CBSAs.

(b) *Exclusions.* CMS excludes from the selection of geographic areas CBSAs that meet any of the following criteria:

(1) Are located entirely in the State of Maryland.

(2) Are located partially in Maryland, and in which more than 50 percent of the five episode categories tested in TEAM were initiated at a Maryland hospital between January 1, 2022 and June 30, 2023.

(3) Did not have at least one episode for at least one of the five episode categories tested in TEAM between January 1, 2022 and June 30, 2023.

(c) *Stratification.* CMS stratifies the CBSAs that are not excluded in accordance with paragraph (b) of this section into ''high'' and ''low'' categories based four characteristics. CMS then stratifies the CBSAs into mutually exclusive groups corresponding to the 16 unique combinations of high and low values, based on the median, across the four characteristics. CMS then moves outlier CBSAs with a very high number of safety net hospitals into a separate group and thereby creates a total of 17 mutually exclusive stratified groups. The four characteristics are as follows:

(1) Average episode spend for a broad set of episode categories tested in the

BPCI Advanced Model, as described in § 512.505, between January 1, 2022 and June 30, 2023.

(2) Number of acute care hospitals paid under the IPPS between January 1, 2022 and June 30, 2023.

(3) Past exposure to Bundled Payments for Care Improvement (BPCI) Models 2, 3, and 4, as described in § 512.505, Comprehensive Care for Joint Replacement (CJR) as described in § 512.505, or BPCI Advanced between October 1, 2013 and December 31, 2022.

(4) Number of Safety Net hospitals in 2022 that have initiated at least one episode between January 1, 2022 and June 30, 2023 for at least one of the five episode categories tested in TEAM.

(d) *Random selection.* CMS randomly selects CBSAs from the 17 stratified groups, with a higher chance of selection for those CBSAs with a high number of safety net hospitals or low past exposure to bundles and a lower chance of selection for all other CBSAs.

§ 512.520 Participation tracks.

(a) *For performance year 1:* (1) The TEAM participant may choose to participate in Track 1 or Track 3.

(2) The TEAM participant must notify CMS of its track choice, prior to performance year 1, in a form and manner and by a date specified by CMS.

(3) CMS assigns the TEAM participant to Track 1 for performance year 1 if a TEAM participant does not choose a track in the form and manner and by the date specified by CMS.

(b) *For performance years 2 through 5:* (1) CMS assigns a TEAM participant to participate in Track 3 unless the TEAM participant requests to participate in Track 2 and receives approval from CMS to participate in Track 2.

(2) The TEAM participant must notify CMS of its Track 2 request prior to performance year 2, and prior to every performance year thereafter, in a form and manner and by a date specified by CMS.

(3) CMS does not approve a TEAM participant's request to participate in Track 2 submitted in accordance with paragraph (b)(2) of this section unless the TEAM participant is one of the following hospital types at the time of the request:

(i) Medicare-dependent hospital (as defined in § 512.505).

(ii) Rural hospital (as defined in § 512.505).

(iii) Safety Net hospital (as defined in § 512.505).

(iv) Sole community hospital (as defined in § 512.505).

(v) Essential access community hospital (as defined in § 512.505).

(4) A TEAM participant who does not notify CMS of its Track 2 request prior to a given performance year in the form and manner and by the date specified by CMS or who is not one of the hospital types specified in paragraph (b)(3) of this section at the time of the request is assigned to Track 3 for the applicable performance year.

§ 512.522 APM options.

(a) *TEAM APM options.* For performance years 1 through 5, a TEAM participant may choose either of the following options based on their CEHRT use and track participation:

(1) *AAPM option.* A TEAM participant participating in Track 2 or Track 3 may select the AAPM option by attesting in a form and manner and by a date specified by CMS to their use of CEHRT, as defined in § 414.1305 of this chapter, on an annual basis prior to the start of each performance year.

(i) A TEAM participant that selects the AAPM option as provided for in paragraph (a)(1) must provide their CMS electronic health record certification ID in a form and manner and by a date specified by CMS on annual basis prior to the end of each performance year.

(ii) A TEAM participant that selects the AAPM option as provided for in paragraph (a)(1) must retain documentation of their attestation to CEHRT use and provide access to the documentation in accordance with § 512.586.

(2) *Non-AAPM option.* CMS assigns the TEAM participant to the non-AAPM option if the TEAM participant is in Track 1 or if the TEAM participant is in Track 2 or Track 3 and does not attest in a form and manner and by a date specified by CMS to their use of CEHRT as defined in § 414.1305 of this chapter.

(b) *Financial arrangements list.* A TEAM participant with TEAM collaborators, collaboration agents, or downstream collaboration agents during a performance year must submit to CMS a financial arrangements list in a form and manner and by a date specified by CMS on a quarterly basis for each performance year. The financial arrangements list must include the following:

(1) *TEAM collaborators.* For each physician, nonphysician practitioner, or therapist who is a TEAM collaborator during the performance year:

(i) The name, TIN, and NPI of the TEAM collaborator.

(ii) The start date and, if applicable, end date, for the sharing arrangement between the TEAM participant and the TEAM collaborator.

(2) *Collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a collaboration agent during the performance year:

(i) The name, TIN, and NPI of the collaboration agent and the name and TIN of the TEAM collaborator with which the collaboration agent has entered into a distribution arrangement.

(ii) The start date and, if applicable, end date, for the distribution arrangement between the TEAM collaborator and the collaboration agent.

(3) *Downstream collaboration agents.* For each physician, nonphysician practitioner, or therapist who is a downstream collaboration agent during the performance year:

(i) The name, TIN, and NPI of the downstream collaboration agent and the name and TIN of the collaboration agent with which the downstream collaboration agent has entered into a downstream distribution arrangement.

(ii) The start date and, if applicable, end date, for the downstream distribution arrangement between the collaboration agent and the downstream collaboration agent.

(c) *Clinician engagement list.* A TEAM participant must submit to CMS a clinician engagement list in a form and manner and by a date specified by CMS on a quarterly basis during each performance year. The clinician engagement list must include the following:

(1) For each physician, nonphysician practitioner, or therapist who is not on a TEAM participant's financial arrangements list during the performance year but who does have a contractual relationship with the TEAM participant and participates in TEAM activities during the performance year:

(i) The name, TIN, and NPI of the physician, nonphysician practitioner, or therapist.

(ii) The start date and, if applicable, the end date for the contractual relationship between the physician, nonphysician practitioner, or therapist and the TEAM participant.

(d) *Attestation to no individuals.* A TEAM participant with no individuals that meet the criteria specified in paragraphs (b)(1) through (3) of this section for the financial arrangements list or paragraph (c) of this section for the clinician engagement list must attest in a form and manner and by a date specified by CMS that there are no financial arrangements or clinician engagements to report.

(e) *Documentation requirements.* A TEAM participant that submits a financial arrangements list specified in paragraph (b) of this section or a clinician engagement list specified in paragraph (c) of this section must retain and provide access to the documentation in accordance with § 512.586.

Scope of Episodes Being Tested

§ 512.525 Episodes.

(a) *Time periods.* All episodes must begin on or after January 1, 2026 and end on or before December 31, 2030.

(b) *Episode attribution.* All items and services included in the episode are attributed to the TEAM participant at which the anchor hospitalization or anchor procedure, as applicable, occurs.

(c) *Episode initiation.* An episode is initiated by—

(1) A beneficiary's admission to a TEAM participant for an anchor hospitalization that is paid under a MS–DRG specified in paragraph (d) of this section; or

(2) A beneficiary's receipt of an anchor procedure billed under a HCPCS code specified in paragraph (d) of this section. If an anchor hospitalization is initiated on the same day as or within 3 days of an outpatient procedure for the same episode category, the episode start date will be that of the outpatient procedure rather than the admission date, and an anchor procedure will not be initiated.

(d) *Episode categories.* The MS–DRGs and HCPCS codes included in the episodes are as follows:

(1) *Lower extremity joint replacement (LEJR):*

(i) IPPS discharge under MS–DRG 469, 470, 521, or 522; or

(ii) OPPS claim for HCPCS codes 27447, 27130, or 27702.

(2) *Surgical hip/femur fracture treatment (SHFFT).* IPPS discharge under MS–DRG 480 to 482.

(3) *Coronary artery bypass graft (CABG).* IPPS discharge under MS–DRG 231 to 236.

(4) *Spinal fusion:*

(i) IPPS discharge under MS–DRG 453, 454, 455, 459, 460, 471, 472, 473; or

(ii) OPPS claim for HCPCS codes 22551, 22554, 22612, 22630, or 22633.

(5) *Major bowel procedure.* IPPS discharge under MS–DRG 329 to 331.

(e) *Included services.* All Medicare Part A and B items and services are included in the episode, except as specified in paragraph (f) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals, except for those excluded under paragraph (f) of this section.

(13) Hospice services.

(14) Part B professional claims dated in the 3 days prior to an anchor hospitalization if a claim for the surgical procedure for the same episode category is not detected as part of the hospitalization because the procedure was performed by the TEAM participant on an outpatient basis but the patient was subsequently admitted as an inpatient.

(f) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Select items and services considered unrelated to the anchor hospitalization or the anchor procedure for episodes in the baseline period and performance year, including, but not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Organ transplant.

(D) Ventricular shunt.

(ii) Inpatient hospital admissions that fall into the following Major Diagnostic Categories (MDCs):

(A) MDC 02 (Diseases and Disorders of the Eye).

(B) MDC 14 (Pregnancy, Childbirth, and Puerperium).

(C) MDC 15 (Newborns).

(D) MDC 25 (Human Immunodeficiency Virus).

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter for episodes in the baseline period and performance year.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter for episodes initiated in the baseline period and performance year.

(4) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter for episodes in the baseline period and performance year.

(5) Part B payments for low-volume drugs, high-cost drugs and biologicals, and blood clotting factors for hemophilia for episodes in the baseline period and performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biological HCPCS codes that are billed in fewer than 31 episodes in total across all episodes in TEAM during the baseline period;

(ii) Drug/biological HCPCS codes that are billed in at least 31 episodes in the baseline period and have a mean cost of greater than $25,000 per episode in the baseline period; and

(iii) HCPCS codes corresponding to clotting factors for hemophilia patients, identified in the quarterly average sales price file for certain Medicare Part B drugs and biologicals as HCPCS codes with clotting factor equal to 1, HCPCS codes for new hemophilia clotting factors not included in the baseline period, and other HCPCS codes identified as hemophilia.

(6) Part B payments, in addition to those listed in paragraph (f)(5) of this section, for low-volume drugs, high-cost drugs and biologicals, and blood clotting factors for hemophilia for episodes initiated in the performance year, billed on outpatient, carrier, and DME claims, defined as—

(i) Drug/biological HCPCS codes that were not captured in the baseline period and appear in 10 or fewer episodes in the performance year;

(ii) Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, and have a mean cost of greater than $25,000 per episode in the performance year; and

(iii) Drug/biological HCPCS codes that were not included in the baseline period, appear in more than 10 episodes in the performance year, have a mean cost of $25,000 or less per episode in the performance year, and correspond to a drug/biological that appears in the baseline period but was assigned a new HCPCS code between the baseline period and the performance year.

(iv) HCPCS codes for new hemophilia clotting factors not included in the baseline period.

(g) *List of excluded services.* The list of excluded MS–DRGs, MDCs, and HCPCS codes is posted on the CMS website.

(h) *Updating the list of excluded services.* The list of excluded services is updated through rulemaking to reflect:

(1) Changes to the MS–DRGs under the IPPS.

(2) Coding changes.

(3) Other issues brought to CMS' attention.

§ 512.535 Beneficiary inclusion criteria.

(a) Episodes tested in TEAM include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission for an anchor procedure or anchor hospitalization:

(1) Are enrolled in Medicare Parts A and B.

(2) Are not eligible for Medicare on the basis of having end stage renal disease, as described in § 406.13 of this chapter.

(3) Are not enrolled in any managed care plan (for example, Medicare

Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) Are not covered under a United Mine Workers of America health care plan.

(5) Have Medicare as their primary payer.

(b) The episode is canceled in accordance with § 512.537(b) if at any time during the episode a beneficiary no longer meets all of the criteria in this section.

§ 512.537 Determination of the episode.

(a) *Episode conclusion.* (1) An episode ends on the 30th day following the date of the anchor procedure or the date of discharge from the anchor hospitalization, as applicable, with the date of the anchor procedure or the date of discharge from the anchor hospitalization being counted as the first day in the 30-day post-discharge period.

(b) *Cancellation of an episode.* The episode is canceled and is not included in the reconciliation calculation as specified in § 512.545 if any of the following occur:

(1) The beneficiary ceases to meet any criterion listed in § 512.535.

(2) The beneficiary dies during the anchor hospitalization or the outpatient stay for the anchor procedure.

(3) The episode qualifies for cancellation due to extreme and uncontrollable circumstances. An extreme and uncontrollable circumstance occurs if both of the following criteria are met:

(i) The TEAM participant has a CCN primary address that—

(A) Is located in an emergency area, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act; and

(B) Is located in a county, parish, or tribal government designated in a major disaster declaration or emergency disaster declaration under the Stafford Act.

(ii) The date of admission to the anchor hospitalization or the date of the anchor procedure is during an emergency period (as defined in section 1135(g) of the Act) or in the 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins.

Pricing Methodology

§ 512.540 Determination of preliminary target prices.

(a) *Preliminary target price application.* CMS establishes preliminary target prices for TEAM participants for each performance year of the model as follows:

(1) *MS–DRG/HCPCS episode type.* CMS uses the MS–DRGs and, as applicable, HCPCS codes specified in § 512.525(d) when calculating the preliminary target prices for each MS–DRG/HCPCS episode type.

(i) CMS determines a separate preliminary target price for each of the 24 MS–DRGs specified in § 512.525(d).

(ii) Preliminary target prices for a subset of the MS–DRGs specified in § 512.525(d) include certain HCPCS codes as follows:

(A) HCPCS 27130 and 27447 are included in MS–DRG 470

(B) HCPCS 27702 is included in MS–DRG 469.

(C) HCPCS 22633 is included in MS–DRG 455.

(D) HCPCS 22612 and 22630 are included in MS–DRG 460.

(E) HCPCS 22551 and 22554 are included in MS–DRG 473.

(2) *Applicable time period for preliminary target prices.* CMS calculates preliminary target prices for each MS–DRG/HCPCS episode type and region for each performance year and applies the preliminary target price to each episode based on the episode's date of discharge from the anchor hospitalization or the episode's date of the anchor procedure, as applicable.

(3) *Episodes that begin in one performance year and end in the subsequent performance year.* CMS applies the preliminary target price to the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable, but reconciles the episode based on the end date of the episode.

(b) *Preliminary target price calculation.*

(1) CMS calculates preliminary target prices based on average baseline episode spending for the region where the TEAM participant is located.

(i) The region used for calculating the preliminary target price corresponds to the U.S. Census Division associated with the primary address of the CCN of the TEAM participant, and the regional episode spending amount is based on all hospitals in the region, except as specified in § 512.540(b)(1)(ii).

(ii) In cases where a TEAM participant is located in a CBSA selected for participation in TEAM which spans more than one region, the TEAM participant and all other hospitals in the CBSA will be grouped into the region where the most populous city in the CBSA is located for pricing and payment calculations.

(2) CMS uses the following baseline periods to determine baseline episode spending:

(i) *Performance Year 1:* Episodes beginning on January 1, 2022 through December 31, 2024.

(ii) *Performance Year 2:* Episodes beginning on January 1, 2023 through December 31, 2025.

(iii) *Performance Year 3:* Episodes beginning on January 1, 2024 through December 31, 2026.

(iv) *Performance Year 4:* Episodes beginning on January 1, 2025 through December 31, 2027.

(v) *Performance Year 5:* Episodes beginning on January 1, 2026 through December 31, 2028.

(3) CMS calculates the benchmark price as the weighted average of baseline episode spending, applying the following weights:

(i) Baseline episode spending from baseline year 1 is weighted at 17 percent.

(ii) Baseline episode spending from baseline year 2 is weighted at 33 percent.

(iii) Baseline episode spending from baseline year 3 is weighted at 50 percent.

(4) *Exception for high episode spending.* CMS applies a high-cost outlier cap to baseline episode spending at the 99th percentile of regional spending for each of the MS–DRG/HCPCS episode types specified in § 512.540(a)(1)(ii).

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain Medicare incentive programs and add-on payments are excluded from baseline episode spending by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(6) *Prospective normalization factor.* Based on the episodes in the most recent calendar year of the baseline period, CMS calculates a prospective normalization factor, which is a multiplier that ensures that the average risk adjusted target price does not exceed the average unadjusted target price, by doing the following:

(i) CMS applies risk adjustment multipliers, as specified in § 512.545(a)(1) through (3), to the most recent baseline year episodes to calculate the estimated risk-adjusted target price for all performance year episodes.

(ii) CMS divides the mean of the preliminary target price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted

target price calculated in § 512.540(b)(6)(i) for the same episode types across all hospitals and regions.

(7) *Prospective trend factor.* CMS calculates the average regional episode spending for each MS–DRG/HCPCS episode type using the most recent calendar year of the applicable baseline period. CMS then calculates the difference between the average regional spending for each MS–DRG/HCPCS episode type during the most recent calendar year of the baseline period and the average regional spending for each MS–DRG/HCPCS episode type during the first years of the baseline period to determine the prospective trend factor.

(8) *Communication of preliminary target prices.* CMS communicates the preliminary target prices for each MS–DRG/HCPCS episode type for each region to the TEAM participant before the performance year in which they apply.

(c) *Discount factor.* CMS incorporates a discount factor of 3 percent to the TEAM participant's preliminary episode target prices intended to reflect Medicare's potential savings from TEAM.

§ 512.545 Determination of reconciliation target prices.

CMS calculates the reconciliation target price as follows:

(a) CMS risk adjusts the preliminary episode target prices computed under § 512.540 at the beneficiary level using a TEAM Hierarchical Condition Category (HCC) count risk adjustment factor, an age bracket risk adjustment factor, and a social need risk adjustment factor.

(1) The TEAM HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions based on a 90-day lookback period that begins 91 days prior to the anchor hospitalization or anchor procedure and ends on the day prior to the anchor hospitalization or anchor procedure.

(2) The age bracket risk adjustment factor uses four variables, representing beneficiaries in the following age groups as of the first day of the episode:

(i) Less than 65 years.

(ii) 65 to less than 75 years.

(iii) 75 years to less than 85 years.

(iv) 85 years or more.

(3) The social need risk adjustment factor uses two variables, representing beneficiaries that, as of the first day of the episode—

(i) Meet one or more of the following measures of social need:

(A) State ADI above the 8th decile.

(B) National ADI above the 80th percentile.

(C) Eligibility for the low-income subsidy.

(D) Eligibility for full Medicaid benefits.

(ii) Do not meet any of the three measures of social need in § 512.545(a)(1)(iii)(A).

(b) All risk adjustment factors are computed prior to the start of the performance year via a linear regression analysis. The regression analysis is computed using 3 years of claims data as follows:

(1) For performance year 1, CMS uses claims data with dates of service dated January 1, 2022 to December 31, 2024.

(2) For performance year 2, CMS uses claims data with dates of service dated January 1, 2023 to December 31, 2025.

(3) For performance year 3, CMS uses claims data with dates of service dated January 1, 2024 to December 31, 2026.

(4) For performance year 4, CMS uses claims data with dates of service dated January 1, 2025 to December 31, 2027.

(5) For performance year 5, CMS uses claims data with dates of service dated January 1, 2026 to December 30, 2028.

(c) The annual linear regression analysis produces exponentiated coefficients to determine the anticipated marginal effect of each risk adjustment factor on episode costs. CMS transforms, or exponentiates, these coefficients, and the resulting coefficients are the TEAM HCC count risk adjustment factor, the age bracket risk adjustment factor, and the social need risk adjustment factor that would be used during reconciliation for the subsequent performance year.

(d) At the time of reconciliation, the preliminary target prices computed under § 512.540 are risk adjusted at the beneficiary level by applying the applicable TEAM HCC count risk adjustment factor, the age bracket risk adjustment factor, and the social need risk adjustment factor specific to the beneficiary in the episode, as set forth in paragraph (a)(1) of this section.

(e) The risk-adjusted preliminary target prices are normalized at reconciliation to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price.

(1) The final normalization factor at reconciliation—

(i) Is the national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type.

(ii) As applied, cannot exceed + / − 5 percent of the prospective normalization factor (as specified in § 512.540(b)(7)).

(2) CMS applies the final normalization factor to the previously calculated, beneficiary level, risk-adjusted target prices specific to each region and MS–DRG/HCPCS episode type (as specified in paragraph (a)(4) of this section) to calculate the reconciliation target prices, which are compared to performance year spending at reconciliation, as specified in § 512.550(c).

Quality Measures and Composite Quality Score

§ 512.547 Quality measures, composite quality score, and display of quality measures.

(a) *Quality measures.* CMS calculates the quality measures used to evaluate the TEAM participant's performance using Medicare claims data or patient-reported outcomes data that requires no action or reporting by the TEAM participants beyond what is currently required in the Hospital Inpatient Quality Reporting Program and the Hospital-Acquired Condition Reduction Program. The following quality measures are used for public reporting and for determining the TEAM participant's CQS as described in paragraph (b) of this section:

(1) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356);

(2) For all episode categories: CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135); and

(3) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618).

(b) *Calculation of the composite quality score (CQS).* (1) CMS converts the TEAM participant's raw quality measure score for the performance year into a scaled quality measure score by comparing the raw quality measure score to the distribution of raw quality measure score percentiles among a national cohort of hospitals, consisting of TEAM participants and hospitals not participating in TEAM, in the CQS baseline period.

(i) CMS assigns a scaled quality measure score equal to the percentile to which the TEAM Participant's raw quality measure score would have belonged in the CQS baseline period.

(A) CMS assigns the higher scaled quality measure score if the TEAM participant's raw quality measure score straddles two percentiles in the CQS baseline period.

(B) CMS assigns a scaled quality measure score of 100 if the TEAM

participant's raw quality measure score is greater than the maximum of the raw quality measure scores in the CQS baseline period.

(C) CMS assigns a scaled quality measure score of 0 if the raw quality measure score is less than the minimum of the raw quality measure scores in the baseline period.

(D) CMS does not assign a scaled quality measure score if the TEAM participant has no raw quality measure score.

(2) CMS calculates a normalized weight for each quality measure by dividing the TEAM participant's volume of attributed episodes for a given quality measure by the total volume of all the TEAM participant's attributed episodes.

(3) CMS calculates a weighted scaled score for each quality measure by multiplying each quality measure's scaled quality measure score, computed under paragraph (b)(2) of this section, by its normalized weight, computed under paragraph (b)(3) of this section.

(4) CMS sums each quality measure's weighted scaled score, computed under paragraph (b)(4) of this section, to construct the CQS.

(c) *Display of quality measures.* (1) CMS displays quality measure results on the publicly available CMS website that is specific to TEAM, in a form and manner consistent with other publicly reported measures.

(2) CMS shares quality measures with the TEAM participant prior to display on the CMS website.

(3) CMS uses the following time periods to share quality measure performance:

(i) Quality measure performance in performance year 1 is reported in 2027.

(ii) Quality measure performance in performance year 2 is reported in 2028.

(iii) Quality measure performance in performance year 3 is reported in 2029.

(iv) Quality measure performance in performance year 4 is reported in 2030.

(v) Quality measure performance in performance year 5 is reported in 2031.

Reconciliation and Review Process

§ 512.550 Reconciliation process and determination of the reconciliation payment or repayment amount.

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing Medicare rules.

(b) *Reconciliation process.* Six months after the end of each performance year, CMS does the following:

(1) Performs a reconciliation calculation to establish a reconciliation payment or repayment amount for each TEAM participant.

(2) For TEAM participants that experience a reorganization event in which one or more hospitals reorganize under the CCN of a TEAM participant, performs—

(i) Separate reconciliation calculations for each predecessor TEAM participant for episodes where the anchor hospitalization admission or the anchor procedure occurred before the effective date of the reorganization event; and

(ii) Reconciliation calculations for each new or surviving TEAM participant for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event.

(c) *Calculation of the reconciliation amount.* CMS compares the reconciliation target prices described in § 512.545 and the TEAM participant's performance year spending to establish a reconciliation amount for the TEAM participant for each performance year as follows:

(1) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) using claims data that is available 6 months after the end of the performance year.

(2) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.540(b)(4) to performance year episode spending.

(3) CMS applies the adjustments specified in § 512.545 to the preliminary target prices computed in accordance with § 512.540 to calculate the reconciliation target prices.

(4) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)).

(5) CMS subtracts the performance year spending amount determined under paragraph (c)(1–2) of this section from the aggregated reconciliation target price amount determined under paragraph (c)(4) of this section to determine the reconciliation amount.

(d) *Calculation of the quality-adjusted reconciliation amount.* CMS adjusts the reconciliation amount based on the Composite Quality Score as follows:

(1) CMS calculates a CQS adjustment percentage based on a TEAM participant's CQS, computed in accordance with § 512.547(b).

(i) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts for TEAM participants in Track 1.

(ii) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts and up to 15 percent for negative reconciliation amounts for TEAM participants in Track 2.

(iii) CMS applies a CQS adjustment percentage up to 10 percent for positive reconciliation amounts and up to 10 percent for negative reconciliation amounts for TEAM participants in Track 3.

(2) CMS multiplies the CQS adjustment percentage, computed under paragraph (d)(1) of this section, by the TEAM participant's positive or negative reconciliation amount calculated in paragraph (c) of this section to construct the CQS adjustment amount.

(3) CMS subtracts the CQS adjustment amount, computed from paragraph (d)(2) of this section, from the positive or negative reconciliation amount calculated in paragraph (c) of this section to construct the quality-adjusted reconciliation amount.

(e) *Calculation of the net payment reconciliation amount (NPRA).* CMS applies stop-loss and stop gain limits to the quality-adjusted reconciliation amount computed in paragraph (d) of this section to calculate the NPRA as follows:

(1) *Limitation on loss.* For TEAM participants in Track 3, except as provided in paragraph (e)(3) of this section, the repayment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in paragraph (c)(3) of this section for the performance year. The post-episode spending calculation amount in paragraph (f) of this section is not subject to the limitation on loss.

(2) *Limitation on gain.* For TEAM participants in Tracks 1 or 2, the reconciliation payment amount for a performance year cannot exceed 10 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section for the performance year. For TEAM participants in Track 3, the reconciliation payment amount for a performance year cannot exceed 20 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section for the performance year. The post-episode spending amount calculated in accordance with paragraph (f) of this section is not subject to the limitation on gain.

(3) *Limitation on loss for certain providers.* For performance years 2–5, the repayment amount for a TEAM

participant in Track 2 defined at § 512.505, or a TEAM participant that does not meet the low volume threshold of at least 31 episodes across the applicable 3-year baseline period, cannot exceed 10 percent of the aggregated reconciliation target price amount calculated in accordance with paragraph (c)(3) of this section.

(f) *Post-episode spending calculation.* CMS calculates the post-episode spending amount as follows: If the average post-episode spending amount for a TEAM participant in the performance year being reconciled is greater than 3 standard deviations above the regional average post-episode spending amount for the performance year, then the post-episode spending amount that exceeds 3 standard deviations above the regional average post-episode spending amount for the performance year is subtracted from the NPRA for that performance year.

(g) *Calculation of the reconciliation payment or repayment amount.* (1) CMS applies the results of the post-episode spending calculation set forth in paragraph (f) of this section to the NPRA as follows:

(i) For TEAM participants whose post-episode spending amount does not exceed the limit calculated in paragraph (f) of this section, the reconciliation payment or repayment amount is equal to the NPRA.

(ii) If the TEAM participant's post-episode spending exceeds the limit calculated in paragraph (f) of this section, CMS subtracts the amount of post-episode spending exceeding the limit from the NPRA to calculate the reconciliation payment or repayment amount.

(2) If the amount calculated in paragraph (g)(1) of this section is positive, the TEAM participant is owed a reconciliation payment in that amount, to be paid by CMS in one lump sum payment.

(3) If the amount calculated in paragraph (g)(1) of this section is negative, CMS determines the repayment amount as follows:

(i) For TEAM participants in Track 1 for Performance Year 1, the TEAM participant will not owe a repayment amount.

(ii) For TEAM participants in Track 2 or Track 3 for Performance Years 1–5, the Team participant will owe that amount as a repayment to CMS.

(h) *TEAM reconciliation report.* CMS issues each TEAM participant a TEAM reconciliation report for the performance year. Each TEAM reconciliation report contains the following:

(1) The total performance year spending for the TEAM participant.

(2) The TEAM participant's reconciliation target prices.

(3) The TEAM participant's reconciliation amount.

(4) The TEAM participant's composite quality score calculated in accordance with § 512.547(b).

(5) The TEAM participant's quality-adjusted reconciliation amount.

(6) The stop-loss and stop-gain limits that apply to the TEAM participant.

(7) The TEAM participant's NPRA.

(8) The TEAM participant's post-episode spending amount, if applicable.

(9) The amount of any reconciliation payment owed to the TEAM participant or repayment owed by the TEAM participant to CMS for the performance year, if applicable.

§ 512.552 Treatment of incentive programs or add-on payments under existing Medicare payment systems.

The TEAM does not replace any existing Medicare incentive programs or add-on payments. The TEAM payments are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

§ 512.555 Proration of payments for services that extend beyond an episode.

(a) *General.* CMS prorates services included in the episode that extend beyond the episode so that only those portions of the services that were furnished during the episode are included in the calculation of the actual episode payments.

(b) *Proration of services.* CMS prorates payments for services that extend beyond the episode for the purposes of calculating both baseline episode spending and performance year spending using the following methodology:

(1) *Non-IPPS inpatient services.* Non-IPPS inpatient services that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) *Home health agency services.* Home health agency services paid under the Medicare prospective payment system in accordance with part 484, subpart E of this chapter that extend beyond the episode are prorated according to the percentage of days, starting with the first billable service date and through and including the last billable service date, that occur during the episode.

(3) *IPPS services.* IPPS services that extend beyond the end of the episode are prorated according to the MS–DRG geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the full MS–DRG payment is allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the MS–DRG geometric mean length of stay, the MS–DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(4) If the full amount of the payment is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 512.550(f)).

§ 512.560 Appeals process.

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in § 512.594, if a TEAM participant wishes to dispute calculations involving a matter related to payment, reconciliation amounts, repayment amounts, the use of quality measure results in determining the composite quality score, or the application of the composite quality score during reconciliation, the TEAM participant is required to provide written notice of the calculation error, in a form and manner and by a date specified by CMS.

(1) Unless the TEAM participant provides such written notice, CMS deems the TEAM reconciliation report to be final 30 calendar days after it is issued and proceeds with the payment or repayment processes as applicable.

(2) If CMS receives a notice of a calculation error within 30 calendar days of the issuance of the TEAM reconciliation report, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct. CMS reserves the right to extend the time for its response upon written notice to the TEAM participant.

(3) Only TEAM participants may use the calculation error process described in this part.

(b) *Exception to the appeals process.* If the TEAM participant contests a matter that does not involve an issue contained in, or a calculation that contributes to, a TEAM reconciliation report, a notice of calculation error is not required. In these instances, if CMS does not receive a request for reconsideration from the TEAM participant within 10 calendar days of the notice of the initial reconciliation,

the initial determination is deemed final and CMS proceeds with the action indicated in the initial determination. This does not apply to the limitations on review in § 512.594.

§ 512.561 Reconsideration review processes.

(a) Applicability of this section. This section is applicable only where section 1869 of the Act has been waived or is not applicable for TEAM participants. This section is only applicable to TEAM participants.

(b) Right to reconsideration. The TEAM participant may request reconsideration of a determination made by CMS only if such reconsideration is not precluded by section 1115A(d)(2) of the Act or this subpart.

(1) A request for reconsideration by the TEAM participant must satisfy the following criteria:

(i) The request must be submitted to a designee of CMS (''Reconsideration Official'') who—

(A) Is authorized to receive such requests; and

(B) Did not participate in the determination that is the subject of the reconsideration request or, if applicable, the notice of calculation error process.

(ii) The request must include a copy of the initial determination issued by CMS and contain a detailed, written explanation of the basis for the dispute, including supporting documentation.

(iii) The request must be made within 30 days of the date of the initial determination for which reconsideration is being requested via email to an address as specified by CMS.

(2) Requests that do not meet the requirements of paragraph (b)(1) of this section are denied.

(3) Within 10 business days of receiving a request for reconsideration, the Reconsideration Official sends the parties a written acknowledgement of receipt of the reconsideration request. This acknowledgement sets forth the following:

(i) The review procedures.

(ii) A schedule that permits each party to submit position papers and supporting documentation in support of the party's position for consideration by the reconsideration official.

(4) The TEAM participant must satisfy the notice of calculation error requirements specified in this part before submitting a reconsideration request under paragraph (b) of this section.

(c) *Standards for reconsideration.* (1) The parties must continue to fulfill all responsibilities and obligations under TEAM during the course of any dispute arising under this part.

(2) The reconsideration consists of a review of documentation that is submitted timely and in accordance with the standards specified by the reconsideration official.

(3) The burden of proof is on the TEAM participant to demonstrate to the reconsideration official with clear and convincing evidence that the determination is inconsistent with the terms of this subpart.

(d) *Reconsideration determination.* (1) The reconsideration determination is based solely upon—

(i) Position papers and supporting documentation that are timely submitted to the reconsideration official per the schedule defined in paragraph (b)(3)(ii) and meet the standards for submission under paragraph (b)(1) of this section; and

(ii) Documents and data that were timely submitted to CMS in the required format before CMS made the determination that is the subject of the reconsideration request.

(2) The reconsideration official issues the reconsideration determination to CMS and to the TEAM participant in writing.

(3) Absent unusual circumstances, in which case the reconsideration official reserves the right to an extension upon written notice to the TEAM participant, the reconsideration determination is issued within 60 days of receipt of timely filed position papers and supporting documentation per the schedule defined in paragraph (b)(3)(ii) of this section.

(4) The reconsideration determination is final and binding 30 days after its issuance, unless the TEAM participant or CMS timely requests review of the reconsideration determination in accordance with paragraphs (e)(1) and (2) of this section.

(e) *CMS Administrator review.* The TEAM participant or CMS may request that the CMS Administrator review the reconsideration determination.

(1) The request must be made via email within 30 days of the date of the reconsideration determination to the address specified by CMS.

(2) The request must include a copy of the reconsideration determination and a detailed written explanation of why the TEAM participant or CMS disagrees with the reconsideration determination.

(3) The CMS Administrator promptly sends the parties a written acknowledgement of receipt of the request for review.

(4) The CMS Administrator sends the parties notice of the following:

(i) Whether the request for review is granted or denied.

(ii) If the request for review is granted, the review procedures and a schedule that permits each party to submit a brief in support of the party's position for consideration by the CMS Administrator.

(5) If the request for review is denied, the reconsideration determination is final and binding as of the date the request for review is denied.

(6) If the request for review is granted—

(i) The record for review consists solely of—

(A) Timely submitted briefs and the evidence contained in the record of the proceedings before the reconsideration official; and

(B) Evidence as set forth in the documents and data described in paragraph (d)(1)(ii) of this section;

(ii) The CMS Administrator reviews the record and issues to CMS and to the TEAM participant a written determination; and

(iii) The written determination of the CMS Administrator is final and binding as of the date the written determination is sent.

Data Sharing and Other Requirements

§ 512.562 Data sharing with TEAM participants.

(a) *General.* CMS shares certain beneficiary-identifiable data as described in paragraphs (b), (c), and (e) of this section and certain regional aggregate data as described in paragraph (d) of this section with TEAM participants regarding TEAM beneficiaries and performance under the model.

(b) *Beneficiary-identifiable claims data.* CMS shares beneficiary-identifiable claims data with TEAM participants as follows:

(1) CMS makes available certain beneficiary-identifiable claims data described in paragraph (b)(5) of this section for TEAM participants to request for purposes of conducting health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 regarding their TEAM beneficiaries.

(2) A TEAM participant that wishes to receive beneficiary-identifiable claims data for its TEAM beneficiaries must do all of the following:

(i) Submit a formal request for the data on an annual basis in a manner and form and by a date specified by CMS, indicating their selection of summary beneficiary-identifiable data, raw beneficiary-identifiable data, or both, and attest that—

(A) The TEAM participant is requesting claims data of TEAM

beneficiaries who would be in an episode during the baseline period or performance year, as a HIPAA covered entity.

(B) The TEAM participant's request reflects the minimum data necessary, as set forth in paragraph (c) of this section, for the TEAM participant to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(C) The TEAM participant's use of claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care, improving the quality and efficiency of care, and conducting population-based activities relating to improving health or reducing health care costs that are applied uniformly to all TEAM beneficiaries, in an episode during the baseline period or performance year, and that these data will not be used to reduce, limit or restrict care for specific Medicare beneficiaries.

(ii) Sign and submit a TEAM data sharing agreement, as defined in § 512.505, with CMS as set forth in paragraph (e) of this section.

(3) CMS shares this beneficiary-identifiable claims data with a TEAM participant in accordance with applicable privacy and security laws and established privacy and security protections.

(4) CMS omits from the beneficiary-identifiable claims data any information that is subject to the regulations in 42 CFR part 2 governing the confidentiality of substance use disorder patient records.

(5) The beneficiary-identifiable claims data will include, when available, the following:

(i) Unrefined (raw) Medicare Parts A and B beneficiary-identifiable claims data for TEAM beneficiaries in an episode during the 3-year baseline period and performance year.

(ii) Summarized (summary) Medicare Parts A and B beneficiary-identifiable claims data for TEAM beneficiaries in an episode during the 3-year baseline period and performance year.

(6) CMS makes available the beneficiary-identifiable claims data for retrieval by TEAM participants at the following frequency:

(i) Annually, at least 1 month prior to every performance year for baseline period data, based on the baseline periods described in § 512.540(b)(2).

(ii) Monthly during the performance year and for up to 6 months after the performance year for performance year data.

(c) *Minimum necessary data.* The TEAM participant must limit its request for beneficiary-identifiable data under paragraph (b) of this section to the minimum necessary Parts A and B data elements which may include, but are not limited to the following:

(1) Medicare beneficiary identifier (ID).

(2) Procedure code.

(3) Gender.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) Tax identification number.

(11) National provider identifier.

(d) *Regional aggregate data.* (1) CMS shares regional aggregate data for the 3-year baseline period and performance years with TEAM participants as follows.

(i) CMS shares 3-year baseline period regional aggregate data annually at least 1 month before the performance year, based on the baseline periods described in § 512.540(b)(2).

(ii) CMS shares performance year regional aggregate data on a monthly basis during the performance year and for up to 6 months after the performance year.

(2) Regional aggregate data will—

(i) Be aggregated based on all Parts A and B claims associated with episodes in TEAM for the U.S. Census Division in which the TEAM participant is located.

(ii) Summarize average episode spending for episodes in TEAM in the U.S. Census Division in which the TEAM participant is located.

(iii) Be de-identified in accordance with 45 CFR 164.514(b).

(e) *TEAM data sharing agreement.* (1) A TEAM participant who wishes to retrieve the beneficiary-identifiable data specified in paragraph (b) of this section, must complete and submit, on at least an annual basis, a signed TEAM data sharing agreement, as defined in § 512.505, to be provided in a form and manner and by a date specified by CMS, under which the TEAM participant agrees:

(i) To comply with the requirements for use and disclosure of this beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the TEAM set forth in this part.

(ii) To comply with additional privacy, security, breach notification, and data retention requirements specified by CMS in the TEAM data sharing agreement.

(iii) To contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the TEAM participant to the same terms and conditions to which the TEAM participant is itself bound in its TEAM data sharing agreement with CMS as a condition of the business associate's receipt of the beneficiary-identifiable data retrieved by the TEAM participant under the TEAM.

(iv) That if the TEAM participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the data sharing agreement, CMS may deem the TEAM participant ineligible to retrieve beneficiary-identifiable data under paragraph (b) of this section for any amount of time, and the TEAM participant may be subject to additional sanctions and penalties available under the law.

(2) A TEAM participant must comply with all applicable laws and the terms of the TEAM data sharing agreement in order to retrieve the beneficiary-identifiable data.

§ 512.563 Health equity plans.

(a) The TEAM participant may voluntarily submit a health equity plan to CMS for performance year 1 that includes the elements specified in paragraph (c) of this section,.

(b) For performance years 2 through 5, the TEAM participant must submit a health equity plan in a form and manner and by the dates specified by CMS.

(c) Health equity plans must include the following elements:

(1) Identifies health disparities in the TEAM participant's population of TEAM beneficiaries.

(2) Identifies health equity goals and describes how the TEAM participant will use the health equity goals to monitor and evaluate progress in reducing the identified health disparities.

(3) Describes the health equity plan intervention strategy.

(4) Identifies health equity plan performance measure(s), the data sources used to construct the performance measures, and an approach to monitor and evaluate the measures.

§ 512.564 Referral to primary care services.

(a) A TEAM participant must include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to

discharge from an anchor hospitalization or anchor procedure.

(b) In making the referral described in paragraph (a), the TEAM participant must comply with beneficiary freedom of choice, as described in § 512.582(a) of this subpart.

(c) A TEAM participant that does not comply with paragraph (a) of this section, may be subject to remedial action as described in § 512.592.

Financial Arrangements and Beneficiary Incentives

§ 512.565 Sharing arrangements.

(a) *General.* (1) A TEAM participant may enter into a sharing arrangement with a TEAM collaborator to make a gainsharing payment, or to receive an alignment payment, or both. A TEAM participant must not make a gainsharing payment to a TEAM collaborator or receive an alignment payment from a TEAM collaborator except in accordance with a sharing arrangement.

(2) A sharing arrangement must comply with the provisions of this section and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) TEAM participants must develop, maintain, and use a set of written policies for selecting individuals and entities to be TEAM collaborators.

(i) These policies must contain criteria related to, and inclusive of, the quality of care delivered by the potential TEAM collaborator and the provision of TEAM activities.

(ii) The selection criteria cannot be based directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(iii) A selection criterion that considers whether a potential TEAM collaborator has performed a reasonable minimum number of services that would qualify as TEAM activities, as determined by the TEAM participant, will be deemed not to violate the volume or value standard if the purpose of the criterion is to ensure the quality of care furnished to TEAM beneficiaries.

(4) If a TEAM participant enters into a sharing arrangement, its compliance program must include oversight of sharing arrangements and compliance with the applicable requirements of TEAM.

(b) *Requirements.* (1) A sharing arrangement must be in writing and signed by the parties, and entered into before care is furnished to TEAM beneficiaries under the sharing arrangement.

(2) Participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(3) The sharing arrangement must require the TEAM collaborator and its employees, contractors (including collaboration agents), and subcontractors (including downstream collaboration agents) to comply with all of the following:

(i) The applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees).

(ii) All applicable Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

(iii) All other applicable laws and regulations.

(4) The sharing arrangement must require the TEAM collaborator to have or be covered by a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of TEAM that apply to its role as a TEAM collaborator, including any distribution arrangements.

(5) The sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(6) The board or other governing body of the TEAM participant must have responsibility for overseeing the TEAM participant's participation in TEAM, its arrangements with TEAM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the TEAM model.

(7) The specifics of the agreement must be documented in writing and must be made available to CMS upon request (as outlined in § 512.590).

(8) The sharing arrangement must specify the following:

(i) The purpose and scope of the sharing arrangement.

(ii) The obligations of the parties, including specified TEAM activities and other services to be performed by the parties under the sharing arrangement.

(iii) The date range for which the sharing arrangement is effective.

(iv) The financial or economic terms for payment, including the following:

(A) Eligibility criteria for a gainsharing payment.

(B) Eligibility criteria for an alignment payment.

(C) Frequency of gainsharing or alignment payments.

(D) Methodology and accounting formula for determining the amount of a gainsharing payment or alignment payment.

(9) The sharing arrangement must not—

(i) Induce the TEAM participant, TEAM collaborator, or any employees, contractors, or subcontractors of the TEAM participant or TEAM collaborator to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Restrict the ability of a TEAM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(c) *Gainsharing payment, alignment payment, and internal cost savings conditions and restrictions.* (1) Gainsharing payments, if any, must—

(i) Be derived solely from reconciliation payment amounts, or internal cost savings, or both;

(ii) Be distributed on an annual basis (not more than once per calendar year);

(iii) Not be a loan, advance payment, or payment for referrals or other business; and

(iv) Be clearly identified as a gainsharing payment at the time it is paid.

(2)(i) To be eligible to receive a gainsharing payment, a TEAM collaborator must meet quality of care criteria for the performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment. The quality-of-care criteria must be established by the TEAM participant and directly relate to the episode.

(ii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator other than ACO, PGP, NPPGP, or TGP must have directly furnished a billable item or service to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(iii) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator that is a PGP, NPPGP, or TGP must meet the following criteria:

(A) The PGP, NPPGP, or TGP must have billed for an item or service that was rendered by one or more PGP member, NPPGP member, or TGP member respectively to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment.

(B) The PGP, NPPGP, or TGP must have contributed to TEAM activities and been clinically involved in the care of TEAM beneficiaries during the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of examples where, a PGP, NPPGP, or TGP might have been clinically involved in the care of TEAM beneficiaries includes—

(*1*) Providing care coordination services to TEAM beneficiaries during or after inpatient admission;

(*2*) Engaging with a TEAM participant in care redesign strategies, and actually performing a role in implementing such strategies, that are designed to improve the quality of care for episodes and reduce episode spending; or

(*3*) In coordination with other providers and suppliers (such as PGP members, NPPGP members, or TGP members; the TEAM participant; and post-acute care providers), implementing strategies designed to address and manage the comorbidities of TEAM beneficiaries.

(iv) To be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator that is an ACO must meet the following criteria:

(A) The ACO must have had an ACO provider/supplier that directly furnished, or an ACO participant that billed for, an item or service that was rendered to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment; and

(B) The ACO must have contributed to TEAM activities and been clinically involved in the care of TEAM beneficiaries during the performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount or repayment amount that comprises the gainsharing payment or the alignment payment. A non-exhaustive list of ways in which an ACO might have been clinically involved in the care of TEAM beneficiaries could include—

(*1*) Providing care coordination services to TEAM beneficiaries during and/or after inpatient admission;

(*2*) Engaging with a TEAM participant in care redesign strategies and performing a role in implementing such strategies that are designed to improve the quality of care and reduce spending for episodes; or

(*3*) In coordination with providers and suppliers (such as ACO participants, ACO providers/suppliers, the TEAM participant, and post-acute care providers), implementing strategies designed to address and manage the comorbidities of TEAM beneficiaries.

(3)(i) The methodology for accruing, calculating and verifying internal cost savings will be determined by the TEAM participant; however, the methodology must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(ii) The methodology used to calculate internal cost savings must reflect the actual, internal cost savings achieved by the TEAM participant through the documented implementation of TEAM activities identified by the TEAM participant and must exclude—

(A) Any savings realized by any individual or entity that is not the TEAM participant; and

(B) ''Paper'' savings from accounting conventions or past investment in fixed costs.

(4) The amount of any gainsharing payments must be determined in accordance with a methodology that is based solely on quality of care and the provision of TEAM activities. The methodology may take into account the amount of TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators.

(5) For a performance year, the aggregate amount of all gainsharing payments that are derived from reconciliation payment amounts must not exceed the amount of that year's reconciliation payment amount.

(6) No entity or individual, whether a party to a sharing arrangement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(7) A TEAM participant must not make a gainsharing payment to a TEAM collaborator if CMS has notified the TEAM participant that such TEAM collaborator is subject to any action by CMS, HHS or any other governmental entity, or its designees, for noncompliance with this part or the fraud and abuse laws, for the provision of substandard care to TEAM beneficiaries or other integrity problems, or for any other program integrity problems or noncompliance with any other laws or regulations.

(8) The sharing arrangement must require the TEAM participant to recoup any gainsharing payment that contained funds derived from a CMS overpayment on a reconciliation payment amount or was based on the submission of false or fraudulent data.

(9) Alignment payments from a TEAM collaborator to a TEAM participant may be made at any interval that is agreed upon by both parties, and must not be—

(i) Issued, distributed, or paid prior to the calculation by CMS of a repayment amount; payment;

(ii) Loans, advance payments, or payments for referrals or other business; or

(iii) Assessed by a TEAM participant in the absence of a repayment amount.

(10) The TEAM participant must not receive any amounts under a sharing arrangement from a TEAM collaborator that are not alignment payments.

(11) For a performance year, the aggregate amount of all alignment payments received by the TEAM participant must not exceed 50 percent of the TEAM participant's repayment amount.

(12) The aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant may not be greater than—

(i) With respect to a TEAM collaborator other than an ACO, 25 percent of the TEAM participant's repayment amount.

(ii) With respect to a TEAM collaborator that is an ACO, 50 percent of the TEAM participant's repayment amount.

(13) The amount of any alignment payments must be determined in accordance with a methodology that does not directly account for the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM

participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(14) All gainsharing payments and any alignment payments must be administered by the TEAM participant in accordance with generally accepted accounting principles (GAAP) and Government Auditing Standards (The Yellow Book).

(15) All gainsharing payments and alignment payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(d) *Documentation requirements.* (1) TEAM participants must—

(i) Document the sharing arrangement contemporaneously with the establishment of the arrangement;

(ii) Publicly post (and update on at least a quarterly basis) on a web page on the TEAM participant's website—

(A) Accurate lists of all current TEAM collaborators, including the TEAM collaborators' names and addresses as well as accurate historical lists of all TEAM collaborators.

(B) Written policies for selecting individuals and entities to be TEAM collaborators as required by § 512.565(a)(3).

(iii) Maintain, and require each TEAM collaborator to maintain, contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment that includes, at a minimum:

(A) Nature of the payment (gainsharing payment or alignment payment);

(B) Identity of the parties making and receiving the payment;

(C) Date of the payment;

(D) Amount of the payment; and

(E) Date and amount of any recoupment of all or a portion of a TEAM collaborator's gainsharing payment.

(F) Explanation for each recoupment, such as whether the TEAM collaborator received a gainsharing payment that contained funds derived from a CMS overpayment of a reconciliation payment or was based on the submission of false or fraudulent data.

(2) The TEAM participant must keep records of all of the following:

(i) Its process for determining and verifying its potential and current TEAM collaborators' eligibility to participate in Medicare.

(ii) Its plan to track internal cost savings.

(iii) Information on the accounting systems used to track internal cost savings.

(iv) A description of current health information technology, including systems to track reconciliation payment amounts, repayment amounts, and internal cost savings.

(v) Its plan to track gainsharing payments and alignment payments.

(3) The TEAM participant must retain and provide access to and must require each TEAM collaborator to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.568 Distribution arrangements.

(a) *General.* (1) An ACO, PGP, NPPGP, or TGP that is a TEAM collaborator and has entered into a sharing arrangement with a TEAM participant may distribute all or a portion of any gainsharing payment it receives from the TEAM participant only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of this section and all other applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the distribution arrangement.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any distribution payments from an ACO, from an NPPGP to an NPPGP member, or from a TGP to a TGP member, must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a collaboration agent relative to other collaboration agents.

(6) The amount of any distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a collaboration agent relative to other collaboration agents.

(7) A collaboration agent is eligible to receive a distribution payment only if the collaboration agent furnished or billed for an item or service rendered to a TEAM beneficiary during an episode that was attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment being distributed.

(8) With respect to the distribution of any gainsharing payment received by an ACO, PGP, NPPGP, or TGP, the total amount of all distribution payments for a performance year must not exceed the amount of the gainsharing payment received by the TEAM collaborator from the TEAM participant for the same performance year.

(9) All distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The collaboration agent must retain the ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(11) The distribution arrangement must not—

(i) Induce the collaboration agent to reduce or limit medically necessary items and services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The TEAM collaborator must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 512.586, including all of the following:

(i) The relevant written agreements.

(ii) The date and amount of any distribution payment(s).

(iii) The identity of each collaboration agent that received a distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any distribution payment.

(13) The TEAM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same TEAM participant.

(14) The TEAM collaborator must retain and provide access to and must require collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.570 Downstream distribution arrangements.

(a) *General.* (1) An ACO participant that is a PGP, NPPGP, or TGP and that has entered into a distribution arrangement with a TEAM collaborator that is an ACO, may distribute all or a portion of any distribution payment it receives from the TEAM collaborator only in accordance with a downstream distribution arrangement.

(2) All downstream distribution arrangements must comply with the provisions of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All downstream distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the downstream distribution arrangement.

(2) Participation in a downstream distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The downstream distribution arrangement must require the downstream collaboration agent to comply with all applicable laws and regulations.

(4) The opportunity to make or receive a downstream distribution payment must not be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business otherwise generated by, between or among the TEAM participant, any TEAM collaborator, any collaboration agent, any downstream collaboration agent, or any individual or entity affiliated with a TEAM participant, TEAM collaborator, collaboration agent, or downstream collaboration agent.

(5) The amount of any downstream distribution payments from an NPPGP to an NPPGP member or from a TGP to a TGP member must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(6) The amount of any downstream distribution payments from a PGP must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities and that may take into account the amount of such TEAM activities provided by a downstream collaboration agent relative to other downstream collaboration agents.

(7) A downstream collaboration agent is eligible to receive a downstream distribution payment only if the downstream collaboration agent furnished an item or service to a TEAM beneficiary during an episode that is attributed to the same performance year for which the TEAM participant accrued the internal cost savings or earned the reconciliation payment amount that comprises the gainsharing payment from which the ACO made the distribution payment to the PGP, NPPGP, or TGP that is an ACO participant.

(8) The total amount of all downstream distribution payments made to downstream collaboration agents must not exceed the amount of the distribution payment received by the PGP, NPPGP, or TGP from the ACO.

(9) All downstream distribution payments must be made by check, electronic funds transfer, or another traceable cash transaction.

(10) The downstream collaboration agent must retain his or her ability to make decisions in the best interests of the beneficiary, including the selection of devices, supplies, and treatments.

(11) The downstream distribution arrangement must not—

(i) Induce the downstream collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(12) The PGP, NPPGP, or TGP must maintain contemporaneous documentation regarding downstream distribution arrangements in accordance with § 512.586, including the following:

(i) The relevant written agreements.

(ii) The date and amount of any downstream distribution payment.

(iii) The identity of each downstream collaboration agent that received a downstream distribution payment.

(iv) A description of the methodology and accounting formula for determining the amount of any downstream distribution payment.

(13) The PGP, NPPGP, or TGP may not enter into a downstream distribution arrangement with any PGP member, NPPGP member, or TGP member who has—

(i) A sharing arrangement with a TEAM participant.

(ii) A distribution arrangement with the ACO that the PGP, NPPGP, or TGP is a participant in.

(14) The PGP, NPPGP, or TGP must retain and provide access to, and must require downstream collaboration agents to retain and provide access to, the required documentation in accordance with § 512.586.

§ 512.575 TEAM beneficiary incentives.

(a) *General.* TEAM participants may choose to provide in-kind patient engagement incentives including but not limited to items of technology to TEAM beneficiaries in an episode, subject to the following conditions:

(1) The incentive must be provided directly by the TEAM participant or by an agent of the TEAM participant under the TEAM participant's direction and control to the TEAM beneficiary during an episode.

(2) The item or service provided must be reasonably connected to medical care provided to a TEAM beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (c) of this section, for a TEAM beneficiary in an episode by engaging the TEAM beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the episode.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted, except that a TEAM beneficiary may be made aware of the availability of the items or services at the time the TEAM beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to any Federal health care program, as defined at section 1128B(f) of the Act.

(b) *Technology provided to a TEAM beneficiary.* TEAM beneficiary engagement incentives involving technology are subject to the following additional conditions:

(1) Items or services involving technology provided to a TEAM beneficiary may not exceed $1,000 in retail value for any one TEAM beneficiary during any one episode.

(2) Items or services involving technology provided to a TEAM beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (c) of this section, for a beneficiary in an episode.

(3) Items of technology exceeding $75 in retail value must—

(i) Remain the property of the TEAM participant; and

(ii) Be retrieved from the TEAM beneficiary at the end of the episode, with documentation of the ultimate date of retrieval. The TEAM participant must document all retrieval attempts. In cases when the item of technology is not able to be retrieved, the TEAM participant

must determine why the item was not retrievable. If it was determined that the item was misappropriated (if it were sold, for example), the TEAM participant must take steps to prevent future beneficiary incentives for that TEAM beneficiary. Following this process, documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(c) *Clinical goals of TEAM.* The following are the clinical goals of TEAM, which may be advanced through TEAM beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications following an episode.

(4) Management of chronic diseases and conditions that may be affected by the TEAM procedure.

(d) *Documentation of TEAM beneficiary incentives.* (1) TEAM participants must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be established contemporaneously with the provision of the items and services with a record established and maintained to include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the TEAM beneficiary to whom the item or service was provided.

(3) The documentation regarding items of technology exceeding $75 in retail value must also include contemporaneous documentation of any attempt to retrieve technology at the end of an episode, or why the items were not retrievable, as described in paragraph (b)(3) of this section.

(4) The TEAM participant must retain and provide access to the required documentation in accordance with § 512.586.

§ 512.576 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

(a) *Application of the CMS-sponsored model arrangements safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)(1)) is available to protect remuneration furnished in the TEAM in the form of sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments, and the downstream distribution arrangement's distribution payments that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), and §§ 512.565, 512.568, 512.570.

(b) *Application of the CMS-sponsored model patient incentives safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)(2)) is available to protect TEAM beneficiary incentives that meet all safe harbor requirements set forth in 42 CFR 1001.952(ii) and § 512.575.

Medicare Program Waivers

§ 512.580 TEAM Medicare Program Waivers

(a) *Waiver of certain telehealth requirements*—(1) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in TEAM solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.525(e).

(2) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)I(ii)(I) through (VIII) of the Act for episodes to permit a telehealth visit to originate in the beneficiary's home or place of residence solely for services that—

(i) May be furnished via telehealth under existing Medicare program requirements; and

(ii) Are included in the episode in accordance with § 512.525(e).

(3) *Waiver of selected payment provisions.* (i) CMS waives the payment requirements under section 1834(m)(2)(A) of the Act so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(ii) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to TEAM.

(4) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

(b) *Waiver of the SNF 3-day rule*—(1) *Episodes initiated by an anchor hospitalization.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of discharge from the anchor hospitalization for a beneficiary who is a TEAM beneficiary on the date of discharge from the anchor hospitalization if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the TEAM beneficiary's admission to the SNF.

(2) *Episodes initiated by an anchor procedure.* CMS waives the SNF 3-day rule for coverage of a SNF stay within 30 days of the date of service of the anchor procedure for a beneficiary who is a TEAM beneficiary on the date of service of the anchor procedure if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of the TEAM beneficiary's admission to the SNF.

(3) *Determination of qualified SNFs.* CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(4) *Posting of qualified SNFs.* CMS posts to the CMS website the list of qualified SNFs in advance of the calendar quarter.

(5) *Financial liability for non-covered SNF services.* If CMS determines that the waiver requirements specified in paragraph (b) of this section were not met, the following apply:

(i) CMS makes no payment to a SNF for SNF services if the SNF admits a TEAM beneficiary who has not had a qualifying anchor hospitalization or anchor procedure.

(ii) In the event that CMS makes no payment for SNF services furnished by a SNF as a result of paragraph (5)(i) of this section, the beneficiary protections specified in paragraph (5)(iii) of this section apply, unless the TEAM participant has provided the beneficiary with a discharge planning notice in accordance with § 512.582(b)(3).

(iii) If the TEAM participant does not provide the beneficiary with a discharge planning notice in accordance with § 512.582(b)(3)—

(A) The SNF must not charge the beneficiary for the expenses incurred for such services;

(B) The SNF must return to the beneficiary any monies collected for such services; and

(C) The TEAM participant is financially liable for the expenses incurred for such services.

(4) If the TEAM participant provided a discharge planning notice to the

beneficiary in accordance with § 512.582(b)(3), then normal SNF coverage requirements apply and the beneficiary may be financially liable for non-covered SNF services.

(c) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered services continue to apply except as otherwise waived in this part.

General Provisions

§ 512.582 Beneficiary protections.

(a) *Beneficiary freedom of choice.* (1) A TEAM participant, TEAM collaborators, collaboration agents, downstream collaboration agent and downstream participants must not restrict Medicare beneficiaries' ability to choose to receive care from any provider or supplier.

(2) The TEAM participant and its downstream participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. The TEAM participant and its downstream participants may communicate to TEAM beneficiaries the benefits of receiving care with the TEAM participant, if otherwise consistent with the requirements of this part and applicable law.

(3) As part of discharge planning and referral, TEAM participants must provide a complete list of HHAs, SNFs, IRFs, or LTCHs that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient.

(i) This list must be presented to TEAM beneficiaries for whom home health care, SNF, IRF, or LTCH services are medically necessary.

(ii) TEAM participants must specify on the list those post-acute care providers on the list with whom they have a sharing arrangement.

(iii) TEAM participants may recommend preferred providers and suppliers, consistent with applicable statutes and regulations.

(iv) TEAM participants may not limit beneficiary choice to any list of providers or suppliers in any manner other than as permitted under applicable statutes and regulations.

(v) TEAM participants must take into account patient and family preferences for choice of provider and supplier when they are expressed.

(4) TEAM participants may not charge any TEAM collaborator a fee to be included on any list of preferred providers or suppliers, nor may the TEAM participant accept such payments.

(b) *Required beneficiary notification*—(1) *TEAM participant beneficiary notification*—(i) *Notification to beneficiaries.* Each TEAM participant must provide written notification to any TEAM beneficiary that meets the criteria in § 512.535 of his or her inclusion in the TEAM model.

(ii) *Timing of notification.* Prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure, as applicable, the TEAM participant must provide the TEAM beneficiary with a beneficiary notification as described in paragraph (b)(1)(iv) of this section.

(iii) *List of beneficiaries who have received a notification.* The TEAM participant must be able to generate a list of all beneficiaries who have received such notification, including the date on which the notification was provided to the beneficiary, to CMS or its designee upon request.

(iv) *Content of notification.* The beneficiary notification must contain all of the following:

(A) A detailed explanation of TEAM and how it might be expected to affect the beneficiary's care.

(B) Notification that the beneficiary retains freedom of choice to choose providers and services.

(C) Explanation of how patients can access care records and claims data through an available patient portal, if applicable, and how they can share access to their Blue Button® electronic health information with caregivers.

(D) Explanation of the type of beneficiary-identifiable claims data the TEAM participant may receive.

(E) A statement that all existing Medicare beneficiary protections continue to be available to the TEAM beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations or the 1–800–MEDICARE helpline.

(F) A list of the providers, suppliers, and ACOs with whom the TEAM participant has a sharing arrangement. This requirement may be fulfilled by the TEAM participant including in the detailed notification a Web address where beneficiaries may access the list.

(2) *TEAM collaborator notice.* A TEAM participant must require every TEAM collaborator to provide written notice to applicable TEAM beneficiaries of TEAM, including information on the quality and payment incentives under TEAM, and the existence of its sharing arrangement with the TEAM participant.

(i) With the exception of ACOs, PGPs, NPPGPs, and TGPs, a TEAM participant must require every TEAM collaborator that furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the TEAM collaborator's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from the TEAM collaborator during an episode. In circumstances where, due to the patient's condition, it is not feasible to provide notification at such time, the notification must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The TEAM collaborator must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(ii) A TEAM participant must require every PGP, NPPGP, or TGP that is a TEAM collaborator where a member of the PGP, member of the NPPGP, or member of the TGP furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or service from any member of the PGP, member of the NPPGP, or member of the TGP, and the required PGP, NPPGP, or TGP notice may be provided by that member respectively. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The PGP, NPPGP, or TGP must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(iii) A TEAM participant must require every ACO that is a TEAM collaborator where an ACO participant or ACO provider/supplier furnishes an item or service to a TEAM beneficiary during an episode to provide written notice to the beneficiary of TEAM, including basic information on the quality and payment incentives under TEAM, and the existence of the entity's sharing arrangement. The notice must be provided no later than the time at which the beneficiary first receives an item or

service from any ACO participant or ACO provider/supplier and the required ACO notice may be provided by that ACO participant or ACO provider/supplier respectively. In circumstances where, due to the patient's condition, it is not feasible to provide notice at such times, the notice must be provided to the beneficiary or his or her representative as soon as is reasonably practicable. The ACO must be able to provide a list of all beneficiaries who received such a notice, including the date on which the notice was provided to the beneficiary, to CMS upon request.

(3) *Discharge planning notice.* A TEAM participant must provide the beneficiary with a written notice of any potential financial liability associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged from an anchor procedure or anchor hospitalization, whichever occurs earlier.

(i) If the TEAM participant knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute care service or other non-covered associated service or supply, the TEAM participant must notify the beneficiary in writing that the service would not be covered by Medicare.

(ii) If the TEAM participant is discharging a beneficiary to a SNF after an inpatient hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 512.580, the TEAM participant must notify the beneficiary in accordance with paragraph (b)(3)(i) of this section that the beneficiary will be responsible for payment for the services furnished by the SNF during that stay, except those services that would be covered by Medicare Part B during a non-covered inpatient SNF stay.

(4) *Access to records and retention.* Lists of beneficiaries that receive notifications or notices must be retained, and access provided to CMS, or its designees, in accordance with § 512.586.

(c) *Availability of services.* (1) The TEAM participant and its downstream participants must continue to make medically necessary covered services available to beneficiaries to the extent required by applicable law. TEAM beneficiaries and their assignees retain their rights to appeal claims in accordance with part 405, subpart I of this chapter.

(2) The TEAM participant and its downstream participants must not take any action to select or avoid treating certain Medicare beneficiaries based on their income levels or based on factors that would render the beneficiary an ''at-risk beneficiary'' as defined at § 425.20 of this chapter.

(3) The TEAM participant and its downstream participants must not take any action to selectively target or engage beneficiaries who are relatively healthy or otherwise expected to improve the TEAM participant's or downstream participant's financial or quality performance, a practice commonly referred to as ''cherry-picking.''

(d) *Descriptive TEAM materials and activities.* (1) The TEAM participant and its downstream participants must not use or distribute descriptive TEAM materials and activities that are materially inaccurate or misleading.

(2) The TEAM participant and its downstream participants must include the following statement on all descriptive TEAM materials and activities: ''The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document.''

(3) The TEAM participant and its downstream participants must retain copies of all written and electronic descriptive TEAM materials and activities and appropriate records for all other descriptive TEAM materials and activities in a manner consistent with § 512.135(c).

(4) CMS reserves the right to review, or have a designee review, descriptive TEAM materials and activities to determine whether or not the content is materially inaccurate or misleading. This review takes place at a time and in a manner specified by CMS once the descriptive TEAM materials and activities are in use by the TEAM participant.

§ 512.584 Cooperation in model evaluation and monitoring.

The TEAM participant and its TEAM collaborators must comply with the requirements of § 403.1110(b) of this chapter and must otherwise cooperate with CMS' TEAM evaluation and monitoring activities as may be necessary to enable CMS to evaluate TEAM in accordance with section 1115A(b)(4) of the Act and to conduct monitoring activities under § 512.590, including producing such data as may be required by CMS to evaluate or monitor TEAM, which may include protected health information as defined in 45 CFR 160.103 and other individually-identifiable data.

§ 512.586 Audits and record retention.

(a) *Right to audit.* The Federal government, including CMS, HHS, and the Comptroller General, or their designees, has the right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of TEAM.

(b) *Access to records.* The TEAM participant and its TEAM collaborators must maintain and give the Federal government, including CMS, HHS, and the Comptroller General, or their designees, access to all such documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the implementation of TEAM, including without limitation, documents and other evidence regarding all of the following:

(1) The TEAM participant's and its downstream participants' compliance with the terms of TEAM.

(2) The accuracy of TEAM reconciliation payment amounts and repayment amounts.

(3) The TEAM participant's payment of amounts owed to CMS under TEAM.

(4) Quality measure information and the quality of services performed under the terms of TEAM.

(5) Utilization of items and services furnished under TEAM.

(6) The ability of the TEAM participant to bear the risk of potential losses and to repay any losses to CMS, as applicable.

(7) Patient safety.

(8) Other program integrity issues.

(c) *Record retention.* (1) The TEAM participant and its downstream participants must maintain the documents and other evidence described in paragraph (b) of this section and other evidence for a period of 6 years from the last payment determination for the TEAM participant under TEAM or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the TEAM participant at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant or its downstream participants, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the

termination, dispute, or allegation of fraud or similar fault.

(2) If CMS notifies the TEAM participant of the special need to retain records in accordance with paragraph (c)(1)(i) of this section or there has been a termination, dispute, or allegation of fraud or similar fault against the TEAM participant or its downstream participants described in paragraph (c)(1)(ii) of this section, the TEAM participant must notify its downstream participants of this need to retain records for the additional period specified by CMS.

§ 512.588 Rights in data and intellectual property.

(a) CMS may—

(1) Use any data obtained under §§ 512.584, 512.586, or 512.590 to evaluate and monitor TEAM; and

(2) Disseminate quantitative and qualitative results and successful care management techniques, including factors associated with performance, to other providers and suppliers and to the public. Data disseminated may include patient—

(i) De-identified results of patient experience of care and quality of life surveys, and patient;

(ii) De-identified measure results calculated based upon claims, medical records, and other data sources.

(b) Notwithstanding any other provision of this part, for all data that CMS confirms to be proprietary trade secret information and technology of the TEAM participant or its downstream participants, CMS or its designee(s) will not release this data without the express written consent of the TEAM participant or its downstream participant, unless such release is required by law.

(c) If the TEAM participant or its downstream participant wishes to protect any proprietary or confidential information that it submits to CMS or its designee, the TEAM participant or its downstream participant must label or otherwise identify the information as proprietary or confidential. Such assertions are subject to review and confirmation by CMS prior to CMS' acting upon such assertions.

§ 512.590 Monitoring and compliance.

(a) *Compliance with laws.* The TEAM participant and each of its downstream participants must comply with all applicable laws and regulations.

(b) *CMS monitoring and compliance activities.* (1) CMS staff, or its approved designee, may conduct monitoring activities to ensure compliance by the TEAM participant and each of its downstream participants with the terms of TEAM under this subpart to—

(i) Understand TEAM participants' use of TEAM payments; and

(ii) Promote the safety of beneficiaries and the integrity of TEAM.

(2) Monitoring activities may include, without limitation, all of the following:

(i) Documentation requests sent to the TEAM participant and its downstream participants, including surveys and questionnaires.

(ii) Audits of claims data, quality measures, medical records, and other data from the TEAM participant and its downstream participants.

(iii) Interviews with members of the staff and leadership of the TEAM participant and its downstream participants.

(iv) Interviews with beneficiaries and their caregivers.

(v) Site visits to the TEAM participant and its downstream participants, performed in a manner consistent with paragraph (c) of this section.

(vi) Monitoring quality outcomes and clinical data, if applicable.

(vii) Tracking patient complaints and appeals.

(3) In conducting monitoring and oversight activities, CMS or its designees may use any relevant data or information including without limitation all Medicare claims submitted for items or services furnished to TEAM beneficiaries.

(c) *Site visits.* (1) In a manner consistent with § 512.584, the TEAM participant and its downstream participants must cooperate in periodic site visits performed by CMS or its designees in order to facilitate the evaluation of TEAM and the monitoring of the TEAM participant's compliance with the terms of TEAM.

(2) CMS or its designee provides, to the extent practicable, the TEAM participant or downstream participant with no less than 15 days advance notice of any site visit. CMS—

(i) Attempts, to the extent practicable, to accommodate a request for particular dates in scheduling site visits; and

(ii) Does not accept a date request from a TEAM participant or downstream participant that is more than 60 days after the date of the CMS initial site visit notice.

(3) The TEAM participant and its downstream participants must ensure that personnel with the appropriate responsibilities and knowledge associated with the purpose of the site visit are available during all site visits.

(4) Additionally, CMS may perform unannounced site visits at the office of the TEAM participant and any of its downstream participants at any time to investigate concerns about the health or safety of beneficiaries or other patients or other program integrity issues.

(5) Nothing in this part shall be construed to limit or otherwise prevent CMS from performing site visits permitted or required by applicable law.

(d) *Reopening of payment determinations.* (1) CMS may reopen a TEAM payment determination on its own motion or at the request of a TEAM participant, within 4 years from the date of the determination, for good cause (as defined at § 405.986 of this chapter).

(2) CMS may reopen a TEAM payment determination at any time if there exists reliable evidence (as defined in § 405.902 of this chapter) that the determination was procured by fraud or similar fault (as defined in § 405.902 of this chapter).

(3) CMS's decision regarding whether to reopen a TEAM payment determination is binding and not subject to appeal.

(e) *OIG authority.* Nothing contained in the terms of TEAM limits or restricts the authority of the HHS Office of Inspector General or any other Federal government authority, including its authority to audit, evaluate, investigate, or inspect the TEAM participant or its downstream participants for violations of any Federal statutes, rules, or regulations.

§ 512.592 Remedial action.

(a) *Grounds for remedial action.* CMS may take one or more remedial actions described in paragraph (b) of this section if CMS determines that the TEAM participant or a downstream participant:

(1) Has failed to comply with any of the terms of TEAM, included in this subpart.

(2) Has failed to comply with any applicable Medicare program requirement, rule, or regulation.

(3) Has taken any action that threatens the health or safety of a beneficiary or other patient.

(4) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of TEAM.

(5) Has undergone a change in control that presents a program integrity risk.

(6) Is subject to any sanctions of an accrediting organization or a Federal, State, or local government agency.

(7) Is subject to investigation or action by HHS (including the HHS Office of Inspector General and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including any of the following:

(i) Being subject to the filing of a complaint or filing of a criminal charge.

(ii) Being subject to an indictment.

(iii) Being named as a defendant in a False Claims Act qui tam matter in

which the Federal government has intervened, or similar action.

(8) Has failed to demonstrate improved performance following any remedial action imposed under this section.

(9) Has misused or disclosed beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the applicable data sharing agreement.

(b) *Remedial actions.* If CMS determines that one or more grounds for remedial action described in paragraph (a) of this section has taken place, CMS may take one or more of the following remedial actions:

(1) Notify the TEAM participant and, if appropriate, require the TEAM participant to notify its downstream participants of the violation.

(2) Require the TEAM participant to provide additional information to CMS or its designees.

(3) Subject the TEAM participant to additional monitoring, auditing, or both.

(4) Prohibit the TEAM participant from distributing TEAM payments, as applicable.

(5) Require the TEAM participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to TEAM.

(6) Require the TEAM participant to submit a corrective action plan in a form and manner and by a date specified by CMS.

(7) Discontinue the provision of data sharing and reports to the TEAM participant.

(8) Recoup TEAM payments.

(9) Reduce or eliminate a TEAM payment otherwise owed to the TEAM participant.

(10) Such other action as may be permitted under the terms of this part.

§ 512.594 Limitations on review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

(a) The selection of models for testing or expansion under section 1115A of the Act.

(b) The selection of organizations, sites, or participants to test TEAM, including a decision by CMS to remove a TEAM participant or to require a TEAM participant to remove a downstream participant from TEAM.

(c) The elements, parameters, scope, and duration of testing or dissemination, including without limitation the following:

(1) The selection of quality performance standards for TEAM by CMS.

(2) The methodology used by CMS to assess the quality of care furnished by the TEAM participant.

(3) The methodology used by CMS to attribute TEAM beneficiaries to the TEAM participant, if applicable.

(d) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act.

(e) The termination or modification of the design and implementation of TEAM under section 1115A(b)(3)(B) of the Act.

(f) Determinations about expansion of the duration and scope of TEAM under section 1115A(c) of the Act, including the determination that TEAM is not expected to meet criteria described in paragraph (a) or (b) of this section.

§ 512.595 Bankruptcy and other notifications.

(a) *Notice of bankruptcy.* If the TEAM participant has filed a bankruptcy petition, whether voluntary or involuntary, the TEAM participant must provide written notice of the bankruptcy to CMS and to the U.S. Attorney's Office in the district where the bankruptcy was filed, unless final payment has been made by either CMS or the TEAM participant under the terms of TEAM and all administrative or judicial review proceedings relating to any TEAM payments have been fully and finally resolved. The notice of bankruptcy must be sent by certified mail no later than 5 days after the petition has been filed and must contain a copy of the filed bankruptcy petition (including its docket number). The notice to CMS must be addressed to the CMS Office of Financial Management at 7500 Security Boulevard, Mailstop C3–01–24, Baltimore, MD 21244 or such other address as may be specified on the CMS website for purposes of receiving such notices.

(b) *Notice of legal name change.* A TEAM participant must furnish written notice to CMS within 30 days of any change in its legal name becomes effective. The notice of legal name change must be in a form and manner specified by CMS and must include a copy of the legal document effecting the name change, which must be authenticated by the appropriate State official.

(c) *Notice of change in control.* (1) A TEAM participant must furnish written notice to CMS in a form and manner specified by CMS at least 90 days before any change in control becomes effective.

(2) If CMS determines, in accordance with § 512.592(a)(5), that a TEAM participant's change in control would present a program integrity risk, CMS may—

(i) Take remedial action against the TEAM participant under § 512.160(b).

(ii) Require immediate reconciliation and payment of all monies owed to CMS by a TEAM participant that is subject to a change in control.

§ 512.596 Termination of TEAM or TEAM participant from model by CMS.

(a) *Termination of TEAM.* (1) CMS may terminate TEAM for reasons including, but not limited to, the following:

(i) CMS determines that it no longer has the funds to support TEAM.

(ii) CMS terminates TEAM in accordance with section 1115A(b)(3)(B) of the Act.

(2) If CMS terminates TEAM, CMS provides written notice to the TEAM participant specifying the grounds for termination and the effective date of such termination.

(b) *Notice of a TEAM participant's termination from TEAM.* If a TEAM participant receives notification that it has been terminated from TEAM and wishes to dispute the termination, it must provide a written notice to CMS requesting review of the termination within 10 calendar days of the notice. CMS has 30 days to respond to the TEAM participant's request for review. If the TEAM participant fails to notify CMS, the termination is deemed final.

§ 512.598 Decarbonization and Resilience initiative.

TEAM participants may elect to report questions and metrics related to emissions to CMS on an annual basis following each performance period.

(a) Voluntary Reporting includes the following metrics:

(1) Organizational questions, which are a set of questions about the TEAM participants' sustainability team and sustainability activities.

(2) Building energy metrics, which are a set of metrics related to measuring and reporting GHG emissions related to energy use at TEAM participant facilities.

(i) Building energy metrics are based on the ENERGY STAR® PortfolioManager® guidelines for the time of submission. TEAM participants reporting these metrics must submit using ENERGY STAR Portfolio Manager in manner described in paragraph (b).

(ii) Metrics to be collected include:

(A) ENERGY STAR Score for Hospitals as defined in the ENERGY STAR Portfolio Manager as well as supporting data which may include energy use intensity, electricity, natural

gas, and other source emissions and normalizing factors such as building size, number of full-time equivalent workers, number of staffed beds, number of magnetic resonance imaging machines, zip codes, and heating and cooling days, as specified in the ENERGY STAR Portfolio Manager.

(B) Energy cost, to capture total energy costs, as specified in the ENERGY STAR Portfolio Manager.

(C) Total, direct, and indirect GHG emissions and emissions intensity as specified in the ENERGY STAR Portfolio Manager.

(3) Anesthetic gas metrics, which are a set of metrics related to measuring and managing emissions from anesthetic gas which include all of the following:

(i) Total greenhouse gas emissions from inhaled anesthetics based on purchase records.

(ii) Normalization factors that may include information on anesthetic hours.

(iii) Assessment questions based on key actions recommended for reducing emissions for anesthetic gases.

(4) Transportation metrics, which are a set metrics that focus on greenhouse gases related to leased or owned vehicles and may include any of the following:

(i) Gallons for owned and leased vehicles.

(ii) Normalization factors that may include patient encounter volume.

(iii) Assessment questions on key actions to reduce transportation emissions.

(A) If the TEAM Participant elects to report the metrics in paragraph (a) of this section to CMS, such information must be reported to CMS in a form and manner specified by CMS for each performance year, including the use of ENERGY STAR Portfolio Manager for the building energy metrics at paragraph (a)(2) of this section and a survey and questionnaire for questions and metrics at paragraphs (a)(1), (3), and (4) of this section. If the TEAM participant chooses to participate, the TEAM participant must report the information to CMS no later than 120 days in the year following the performance year, or a later date as specified by CMS.

(B) If a TEAM participant elects to report all the metrics specified in paragraph (a) of this section to CMS, in the manner specified in paragraph (b) of this section, CMS annually provides to the TEAM participant with the following:

(*1*) Individualized feedback reports, which may summarize facilities' emissions metrics and would include benchmarks, as feasible, for normalized metrics to compare facilities, in aggregate, to other TEAM participants in the Decarbonization and Resilience Initiative.

(*2*) Publicly reported hospital recognition for the TEAM participant's commitment to decarbonization through a hospital recognition badge publicly reported on a CMS website.

Xavier Becerra,

Secretary, Department of Health and Human Services.

The following addendum and appendices will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2024, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2024

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2025 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2025. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2024. In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2025.

In general, except for SCHs and MDHs, for FY 2025, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (including, as discussed in section IV.E. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), enacted on December 29, 2022, extended the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024). Subsequently, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, further extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Under current law, the MDH program will expire for discharges on or after January 1, 2025. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

As discussed in section V.B.2. of the preamble of this proposed rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2025. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2025. In section IV. of this Addendum, we are setting forth the rate-

of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2025. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2025. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2025

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2025.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2025, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount.

We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion on the FY 2025 inpatient hospital update. The table that follows shows these four scenarios:

Proposed FY 2025 Applicable Percentage Increase for the IPPS				
FY 2025	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico. In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for FY 2025 and subsequent fiscal years is adjusted by the proposed adjustment for failure to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act. The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for the permanent 10 percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as discussed in section II.D.2.c. of the preamble of this proposed rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2024 budget neutrality factor and applying a revised factor.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.G.5 of the preamble of this proposed rule).
- An adjustment to the standardized amount to implement in a budget neutral manner the wage index cap policy (as described in section III.G.6. of the preamble of this proposed rule).
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Pub. L. 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Pub. L. 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2024 outlier offset and apply an offset for FY 2025, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2025, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of

applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2025 wage index for the rural floor.

For FY 2025, we are proposing to continue to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033).

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2025, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2018-based hospital IPPS market basket) that were used in FY 2024. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2025, as discussed in section III.I. of the preamble of this proposed rule, we are proposing to use a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage increase. Accordingly, we are proposing to calculate the FY 2025 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are proposing to use the 2018-based IPPS operating and capital market baskets for FY 2025. As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2025 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2023 forecast of the hospital market basket percentage increase (as discussed in appendix B of this proposed rule), the forecast of the hospital market basket percentage increase for FY 2025 for this proposed rule is 3.0 percent and the forecast of the productivity adjustment for FY 2025 for this proposed rule is 0.4 percent. As discussed earlier, for FY 2025, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion on the FY 2025 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2025 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2025 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the proposed FY 2025 update factors is set forth in appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2025 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

Section 125 of Division CC (section 125) of the CAA 2021 established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). (We refer the reader to the CMS website at *https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulations/hospitals/rural-emergency-hospitals* for additional information on REHs.) In doing so, section 125 amended section 1861(e) of the Act, which provides the definition of a hospital and states that the term ''hospital'' does not include, unless the context otherwise requires, a critical access hospital (as defined in subsection (mm)(1)) or a rural emergency hospital (as defined in subsection (kkk)(2)). Section 125 also added section 1861(kkk) to the Act, which sets forth the requirements for REHs. Per section 1861(kkk)(2) of the Act, one of the requirements for an REH is that it does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)). Therefore, we believe hospitals that have subsequently converted to REH status should be removed from the calculation of the standardized amount, because they are a separately certified Medicare provider type and are not comparable to other short-term, acute care hospitals as they do not provide inpatient hospital services. For FY 2025, we are proposing to exclude REHs from the calculation of the standardized amount, including hospitals that subsequently became REHs after the period from which the data were taken.

- As in the past, we are proposing to adjust the FY 2025 standardized amount to remove the effects of the FY 2024 geographic reclassifications and outlier payments before applying the FY 2025 updates. We then applied budget neutrality offsets for outliers

and geographic reclassifications to the standardized amount based on proposed FY 2025 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are proposing to remove organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are proposing to not remove revenue center 891 charges from MS–DRG 018 claims during ratesetting because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in the FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2025, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2025, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029 and 59030), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, we are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2025, we are proposing to continue to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment and a proxy based on the prior fiscal year hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). Under this proposed policy for FY 2025, we used the final FY 2024 readmissions adjustment factors from Table 15 of the FY 2024 IPPS/LTCH PPS final rule and the final FY 2024 hospital VBP adjustment factors from Table 16B of the FY 2024 IPPS/LTCH PPS final rule. These proxy factors are applied on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum. We refer the reader to section V.K. of the preamble of this proposed rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.L. of the preamble of this proposed rule for a complete discussion on the Hospital VBP Program.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2025 (as we did for the last 11 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We also are proposing to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

As discussed elsewhere in this proposed rule, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2025. As a result, MDHs that currently receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate plus 75 percent of the difference between payments based on the Federal rate and the hospital-specific rate will be paid based on the Federal rate starting January 1, 2025. Because of the timing of this legislation, the total payments for budget neutrality discussed in this section do not reflect the extension of the MDH program for the first quarter of FY 2025. This extension will be reflected in the total payments for budget neutrality for the final rule. We note, for the final rule, consistent with historical practice for MDHs, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are proposing to continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs under the extension.

• We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2025. Similar to FY 2024, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2025.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges.

We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49414 through 49415), we finalized a change to the ordering of the budget neutrality factors in the calculation so that the RCH Demonstration budget neutrality factor is applied after all wage index and other budget neutrality factors. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

We note that the wage index value is calculated and assigned to a hospital based on the hospital's labor market area. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current statistical areas used in FY 2024 are based on the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, and 18–04. For purposes of determining all of the FY 2024 budget neutrality factors, we determined aggregate payments on each side of the comparison for our budget neutrality calculations using wage indexes based on the current CBSAs.

On July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (*e.g.,* 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). In order to implement these revised standards for the IPPS, it was necessary to identify the new OMB labor market area delineation for each county and hospital in the country. As stated in section III.B. of the preamble of this proposed rule, we believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the IPPS wage index system by more accurately representing current geographic variations in wage levels. As discussed in section III. of the preamble of this proposed rule, we are proposing to adopt the new OMB labor market area delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, effective for the FY 2025 IPPS wage index.

Consistent with our policy to adopt the new OMB delineations, in order to properly determine aggregate payments on each side of the comparison for our budget neutrality calculations, we are proposing to use wage indexes based on the new OMB delineations in the determination of all of the budget neutrality factors discussed later in this section. We also note that, consistent with past practice as finalized in the FY 2005 IPPS final rule (69 FR 49034), we are not adopting the new OMB delineations themselves in a budget neutral manner. We continue to believe that the revision to the labor market areas in and of itself does not constitute an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

a. Proposed Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.D. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2025 proposed rule, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2023 discharge data to simulate payments and compared the following:

• Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the FY 2024 labor-related share percentages, the FY 2024 relative weights, and the FY 2024 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments (as described previously); and

• Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the FY 2024 labor-related share percentages, the proposed FY 2025 relative weights before applying the 10 percent cap, and the FY 2024 pre-reclassified wage data, and applied the same proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2025 relative weights (before applying the 10 percent cap), consistent with our proposal in section V.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2025 relative weights, we are proposing to apply the adjustor for certain MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and other immunotherapies) cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section V.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2025 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2024. Please see the table later in this section setting forth each of the proposed FY 2025 budget neutrality factors.

b. Proposed Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.D.2.c of the preamble of this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900), we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As also discussed in section II.D.2.c of the preamble of this proposed rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we apply a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

To calculate this proposed budget neutrality adjustment factor for FY 2025, we used FY 2023 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the FY 2024 labor-related share percentages, the proposed FY 2025 relative weights before applying the 10-percent cap, and the FY 2024 pre-reclassified wage data, and applied the proposed proxy FY 2025 hospital readmissions payment adjustments and the proposed proxy FY 2025 hospital VBP payment adjustments; and
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the FY 2024 labor-related share percentages, the proposed FY 2025 relative weights after applying the 10-percent cap, and the FY 2024 pre-reclassified wage data, and applied the same proposed proxy FY 2025 hospital readmissions payment adjustments and proposed proxy FY 2025 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2025 relative weights, consistent with our proposal in section V.I. of the preamble to this proposed rule and our historical policy, and as discussed in the preceding section, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2024 to FY 2025. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we are proposing to apply this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2024. Please see the table later in this section setting forth each of the proposed FY 2025 budget neutrality factors.

c. Updated Wage Index—Proposed Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2025, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2023 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 relative weights and the FY 2023 pre-reclassified wage indexes, applied the FY 2024 labor-related share of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proxy FY 2025 hospital readmissions payment adjustment and the proxy FY 2025 hospital VBP payment adjustment.
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 relative weights and the proposed FY 2025 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2025 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proxy FY 2025 hospital readmissions payment adjustments and proxy FY 2025 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the proposed cap (derived in the first step) and the 10 percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2024 to FY 2025. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the proposed FY 2025 budget neutrality factors.

d. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy beginning with FY 2024 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only exclude ''dual reclass'' hospitals (hospitals with simultaneous

§ 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2025, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 labor-related share percentage, the proposed FY 2025 relative weights, and the proposed FY 2025 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proxy FY 2025 hospital readmissions payment adjustments and the proxy FY 2025 hospital VBP payment adjustments.
- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 labor-related share percentage, the proposed FY 2025 relative weights, and the proposed FY 2025 wage data after such reclassifications, and applied the same proxy FY 2025 hospital readmissions payment adjustments and the proxy FY 2025 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2025 and applies the policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this proposed factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the proposed FY 2025 budget neutrality factors.

The proposed FY 2025 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2024 budget neutrality adjustment factor. We note that the proposed FY 2025 budget neutrality adjustment reflects FY 2025 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

e. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2025, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2025 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous to (share a border with) the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2025 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2025 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy beginning with FY 2024 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and are only excluding ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor.

To calculate the proposed national rural floor budget neutrality adjustment factor, we used FY 2023 discharge data to simulate payments, the new OMB labor market area delineations proposed for FY 2025, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The proposed national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2025 budget neutrality factors.

As further discussed in section III.G.2. of this proposed rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2022. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2. of the preamble of this proposed rule for a complete discussion regarding the imputed floor.

f. Proposed Continuation of the Low Wage Index Hospital Policy—Proposed Budget Neutrality Adjustment

As discussed in section III.G.5. of the preamble of this proposed rule, we are proposing to continue for FY 2025 the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3. of this proposed rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are proposing to make a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this proposed budget neutrality adjustment factor for FY 2025, we used FY 2023 discharge data to simulate payments and compared the following:

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 labor-related share percentage, the proposed FY 2025 relative weights, and the proposed FY 2025 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the proposed proxy FY 2025 hospital readmissions

payment adjustments and the proposed proxy FY 2025 hospital VBP payment adjustments; and

- Aggregate payments using the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 labor-related share percentage, the proposed FY 2025 relative weights, and the proposed FY 2025 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proxy FY 2025 hospital readmissions payment adjustments and the proposed proxy FY 2025 hospital VBP payment adjustments applied previously.

This proposed FY 2025 budget neutrality adjustment factor was applied to the standardized amount.

g. Permanent Cap Policy for Wage Index—Proposed Budget Neutrality Adjustment

As noted previously, in section III.G. 6. of the preamble to this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) we finalized a policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also finalized the application of this permanent cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the permanent cap policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2025, we used FY 2023 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the proposed FY 2025 labor-related share percentages, the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 relative weights, the proposed FY 2025 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the proposed proxy FY 2025 hospital readmissions payment adjustments and the proposed proxy FY 2025 hospital VBP payment adjustments.
- Aggregate payments with the 5-percent cap using the proposed FY 2025 labor-related share percentages, the new OMB labor market area delineations proposed for FY 2025, the proposed FY 2025 relative weights, the proposed FY 2025 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proxy FY 2025 hospital readmissions payment adjustments and the proposed proxy FY 2025 hospital VBP payment adjustments applied previously.

We note, Table 2 associated with this proposed rule contains the wage index by provider before and after applying the low wage index hospital policy and the proposed cap.

h. Proposed Rural Community Hospital Demonstration Program Adjustment

In section V.N. of the preamble of this proposed rule, we discuss the Rural Community Hospital (RCH) Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We make an adjustment to the standardized amount to ensure the effects of the RCH Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section V.N. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2025, based on the latest data for this proposed rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $ 49,522,206. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2025, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the Proposed FY 2025 budget neutrality factors. We refer readers to section V.N. of the preamble of this proposed rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

The following table is a summary of the proposed FY 2025 budget neutrality factors, as discussed in the previous sections.

Summary of Proposed FY 2025 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	0.997055
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999617
Wage Index Budget Neutrality Factor	0.999957
Reclassification Budget Neutrality Factor	0.976773
*Rural Floor Budget Neutrality Factor	0.985868
Low Wage Index Hospital Policy Budget Neutrality Factor	0.997498
Cap Policy Wage Index Budget Neutrality Factor	0.997162
Rural Demonstration Budget Neutrality Factor	0.999513

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

i. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the

case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2025 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total projected operating outlier payments by the total projected operating DRG payments plus projected operating outlier payments. As discussed in the next section, for FY 2025, we are incorporating an estimate of the impact of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated total of outlier payments as a proportion of total DRG payments. More information on outlier payments may be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html.*

(1) Proposed Methodology To Incorporate an Estimate of the Impact of Outlier Reconciliation in the FY 2025 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. Instructions for outlier reconciliation are in section 20.1.2.5 of chapter 3 of the Claims Processing Manual (on line at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*). The original instructions issued in July 2003 [853] instruct MACs to identify for CMS any instances where: (1) a hospital's actual operating CCR for the cost reporting period fluctuates plus or minus 10 percentage points or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed; and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. Cost reports that meet these criteria will have the hospital's outlier payments reconciled at the time of cost report final settlement if approved by the CMS Central Office. For the remainder of this discussion, we refer to these criteria as the original criteria for outlier reconciliation (or the original criteria).

On March 28, 2024, we issued Change Request (CR) 13566, which is available at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12558cp*. CR 13566 provides additional instructions to MACs that expand the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. We anticipate that MACs will identify more cost reports to refer to CMS for outlier reconciliation approval. A report issued by the Office of the Inspector General (OIG) recommended that CMS require reconciliation of all hospital outlier payments during a cost-reporting period in its November 2019 report titled ''Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process'' (A–05–16–00060).[854] CMS concurs with the OIG's recommendation.

Consistent with the OIG recommendation, CMS modified the original criteria for identifying cost reports to refer to CMS for outlier reconciliation approval in instructions to MACs in CR 13566. Specifically, CR 13566 states that for cost reports beginning on or after October 1, 2024, MACs shall identify for CMS any instances where: (1) the actual operating CCR is found to be plus or minus 20 percent or more from the operating CCR used during that time period to make outlier payments, and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. For the remainder of this discussion, we refer to these criteria as the new criteria for outlier reconciliation (or the new criteria). We believe the new criteria balance current administrative feasibility with the goal of expanding the scope of cost reports identified for outlier reconciliation approval to increase the accuracy of outlier payments. These new criteria for identifying hospital cost reports that MACs should identify for outlier reconciliation approval are in addition to the original criteria for reconciliation described previously. That is, under the new criteria, MACs identify hospitals for outlier reconciliation that would not have met the original criteria. For example, in an instance where a hospital was paid with an operating CCR of 0.09 and its actual operating CCR was 0.07, then the hospital would not have met the 10-percentage point criterion under the original criteria (the hospital's operating CCR would have to be a negative number, which is not possible). Under the new criteria, a hospital that had a change in their actual operating CCR that was greater than 20 percent from the CCR used for payment during the cost reporting period would be referred to CMS. Using the same example, while the operating CCR changed by a difference of −0.02 percentage point (0.07 minus 0.09), the percentage change operating CCR is −22.2 percent ((0.07/0.09)−1), which meets the new 20 percent criterion. In addition, CR 13566 instructs that for cost reporting periods that begin on or after October 1, 2024, a hospital in its first cost reporting period will be referred for reconciliation of outlier payments at the time of cost report final settlement. As such, new hospitals will be referred for outlier reconciliation regardless of the change to the operating CCR and no matter the amount of outlier payments during the cost reporting period.

If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual for complete instructions regarding outlier reconciliation, including the update to the outlier reconciliation criteria provided in CR 13566.

The regulations at § 412.84(m) further state that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital approved for outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital would owe CMS money. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS would owe the hospital money.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholders' concerns about the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding the incorporation of outlier reconciliation into the outlier fixed loss cost threshold, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule. Consistent with the instructions to MACs that added new criteria that identify additional cost reports for reconciliation beginning with FY 2025 cost reports, we are proposing changes to our methodology to reflect the estimated reconciled outlier payments of the additional hospital cost reports identified under the new criteria. Specifically, we are proposing to make modifications to the steps of our

[853] Change Request 2785 (Transmittal A–03–058; July 3, 2003) found at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/a03058.pdf.*

[854] This report is available on the OIG website at: *https://oig.hhs.gov/oas/reports/region5/51600060.pdf.*

methodology in section II.A.4.i.1.a. of this Addendum to reflect the estimated reconciled outlier payments under the new criteria in the projection of outlier reconciliations for the FY 2025 outlier fixed loss cost threshold.

(a) Incorporating a Proposed Projection of Outlier Reconciliations for the FY 2025 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2025, we are proposing to continue to incorporate outlier reconciliation in the FY 2025 outlier fixed loss cost threshold, with modifications to reflect the expansion of outlier reconciliations under the new criteria in CR 13566 (described previously).

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier reconciliations for the FY 2020 outlier threshold calculation. For FY 2024, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2018 cost reports (cost reports with a begin date on or after October 1, 2017, and on or before September 30, 2018).

Similar to the FY 2024 methodology, we are proposing to determine a projection of outlier reconciliations for the FY 2025 outlier threshold calculation by advancing the historical data used by 1 year. Specifically, we are proposing to use FY 2019 cost reports (cost reports with a begin date on or after October 1, 2018, and on or before September 30, 2019). For FY 2025, we are proposing to use the methodology from FY 2020 to incorporate a projection of operating outlier reconciliations for the FY 2025 outlier threshold calculation, modified to reflect additional cost reports that would be identified for reconciliation under the new criteria in CR 13566. Because the new criteria are not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we are proposing to apply the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement (as described in more detail later in this section).

As described previously, under the expanded outlier reconciliation criteria in CR 13566, for cost reporting periods beginning on or after October 1, 2024, new hospitals will have their outlier payments referred for outlier reconciliation by the MAC to CMS in their first cost reporting period regardless of the change to the operating CCR and no matter the amount of outlier payments during the cost reporting period. For purposes of the methodology for incorporating a projection of operating outlier reconciliations for the FY 2025 outlier threshold calculation to reflect additional cost reports that would be identified for reconciliation under the criteria added by CR 13566, we are not proposing to include the first cost reporting periods of new hospitals because the lack of predictability of new hospitals' data may impact the reliability of our projection. We note we expect the proposed modifications to our methodology for incorporating a projection of operating outlier reconciliations into the outlier threshold calculation would be necessary for 6 years, at which point the additional FY 2025 cost reports with outlier payments reconciled under the new criteria will be reflected in the HCRIS data available to be used to set the threshold.

For FY 2019 hospital cost reports that were reconciled using the original criteria for referral for outlier reconciliation, for this FY 2025 proposed rule, we used the December 2023 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2025 final rule, we propose to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2025, would be the March 2024 extract. As discussed in the FY 2024 IPPS/LTCH final rule (88 FR 59346), we generally expect historical cost reports for the applicable fiscal year to be available by March, and we have worked with our MACs so that historical cost reports for the applicable fiscal year can be made available with the March HCRIS update for the final rule.

To account for the additional hospital cost reports that would be reconciled as a result of the new criteria, we are proposing to use data from the Provider Specific File (PSF) and the cost report to identify the FY 2019 cost reports that would have met the new criteria if those criteria had been in effect. This is because the FY 2019 cost reports in HCRIS would not have been identified as meeting the new criteria for outlier reconciliation since those new criteria are not being used until cost reports beginning with FY 2025. As such, these FY 2019 cost reports do not have an amount reported for operating or capital outlier reconciliation dollars. Therefore, we are proposing to modify our methodology to estimate the outlier reconciliation dollars based on the operating and capital outlier amounts reported on the FY 2019 cost reports and supplemental data collected from the MACs, as described further in this section.

The following proposed steps are similar to those finalized in the FY 2020 final rule, with updated data for FY 2025 and additional steps to reflect the cost reports that would be identified with new criteria under the updated instructions:

Step 1.—Identify hospital cost reports that meet the original criteria or the new criteria.

Step 1a.—Identify hospitals that report on their cost report the operating outlier reconciliation dollars on Worksheet E, Part A, Line 2.01. We note, these were hospitals that were identified by the MACs that met the original criteria for outlier reconciliation and were approved by CMS for outlier reconciliation. We use the Federal FY 2019 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 1b.—For hospitals that were not included in Step 1a, to identify hospitals that would be referred for outlier reconciliation under the new criteria, we are proposing to use data from the latest PSF and cost report data from the most recent publicly available quarterly HCRIS extract. We identified hospitals with cost reports where the actual operating CCR for the cost reporting period fluctuates plus or minus 20 percent or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed. To do this, we compared the operating CCR calculated from the FY 2019 cost report in the most recent publicly available quarterly HCRIS extract (the December 2023 HCRIS for this proposed rule) to the weighted operating CCR used for claim payment during the FY 2019 cost reporting period from the latest quarterly PSF update (December 2023 for this proposed rule). We then determined whether the hospital had total operating and capital outlier payments greater than $500,000 during the FY 2019 cost reporting period based on the most recent publicly available quarterly HCRIS (the December 2023 HCRIS for this proposed rule). If the hospital met both of these criteria, we included the operating outlier payments from the MAC using CCRs from the FY 2019 cost report (as described in Step 2b–2). For the final rule, to identify hospitals that would be referred for reconciliation, we propose to use the most recent HCRIS and PSF data available, which would be the March 2024 update.

Step 2.—Determine the aggregate amount of operating outlier reconciliation dollars (under both the original criteria and the new criteria).

Step 2a.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2019 cost reports from Step 1a.

Step 2b.—For the hospitals that would have met the new criteria as identified in Step 1b, to determine the aggregate amount of operating outlier reconciliation dollars, we propose to use the following process:

We collected supplemental estimated outlier payment data from the MACs for claims with discharges occurring during the hospital's FY 2019 cost reporting period to estimate the change in the hospital's outlier payments. Specifically, for each hospital identified in Step 1b, the MACs used the actual operating CCR calculated from the FY 2019 cost report and the utility in the claims system along with that CCR to determine total outlier payments for claims with discharges occurring during the hospital's FY

2019 cost report (this is the same process MACs would have used if the cost report had been identified for reconciliation had the new criteria been in place for FY 2019 cost reports). For those same claims with discharges occurring during the hospital's 2019 cost report, the MAC provided to CMS the outlier payment as reported on the claim (which was based on the hospital's CCR in the PSF at the time of claim payment).

Using this supplemental estimated outlier payment data, we computed a ratio of the outlier payments based on the actual operating CCR for the FY 2019 cost reporting period and the CCR used at the time of claim payment. This ratio is then applied to the operating outlier payment reported on the FY 2019 cost report to impute an operating outlier payment for the FY 2019 cost report. We believe it is appropriate to impute the operating outlier payment for the cost report using the supplemental data from the MACs described previously rather than use the actual amount reported on the cost report because the claims data in the claims processing system may slightly differ from the cost report data in the HCRIS due to timing. This approach would also allow CMS to use more recent data (from the most recent publicly available quarterly HCRIS extract, which is December 2023 for this proposed rule) to estimate outlier reconciliation dollars as compared to estimating outlier reconciliation dollars using the supplemental outlier payment data from the MACs, which was submitted by the MACs to CMS beginning in November 2022 (as described in this section). This is also the same data used to determine the aggregate amount of operating outlier reconciliation dollars for hospitals from the FY 2019 cost report data using the December 2023 HCRIS extract in Step 2a.

As presented in the table that follows, to calculate the imputed operating outlier payment for the FY 2019 cost report, we multiplied the operating outlier payment reported on the FY 2019 cost report by the following ratio (determined from the supplemental data collected from the MACs described previously): Operating Outlier Payments from MAC using the CCR from FY 2019 Cost Report divided by Operating Outlier Payments from MAC Based on Claim Payment. The general formula is the following: Operating Outlier Payments Reported on the Cost Report * (Operating Outlier Payments from MAC Using CCRs from FY 2019 Cost Report/Operating Outlier Payments from MAC Based on Claim Payment).

To calculate the Estimated Operating Outlier Reconciliation Dollars, we then subtracted the Imputed Operating Outlier Amount for the FY 2019 Cost Report (Step 2b–5) from the Operating Outlier Payment Reported on the FY 2019 Cost Report (Step 2b–1).

The following is an example to illustrate our proposed calculation to determine the estimated amount of operating outlier reconciliation dollars for the hospitals that would have met the new criteria:

	Description	Amount
Step 2b-1	Operating Outlier Payment Reported on the FY 2019 Cost Report	$1,000,000
Step 2b-2	Operating Outlier Payments from MAC Using CCRs from FY 2019 Cost Report	$800,000
Step 2b-3	Operating Outlier Payments from MAC Based on Claim Payment	$975,000
Step 2b-4	Ratio of Step 2b-2 Divided by Step 2b-3	0.82
Step 2b-5	Imputed Operating Outlier Payment for the FY 2019 Cost Report (Step 2b-1 * Step 2b-4)	$820,513
Step 2b-6	Estimated Operating Outlier Reconciliation Dollars (Step 2b-1 - Step 2b-5)	$179,487

We note the following, with regard to the data used in the calculation:

- Due to system limitations the MACs needed 13 months to process all providers' claims through the claims utility (for Steps 2b–;2 and 2b–;3). The MACs used the operating and capital CCR from the FY 2019 cost reports based on the September 2022 HCRIS extract and began processing the supplemental data for FY 2019 outlier payments in November 2022. We propose to move this forward each year, using the September HCRIS for future fiscal years for the CCRs (for example, for FY 2026, MACs would use CCRs from the FY 2020 cost reports based on the September 2023 HCRIS).
- For FY 2025, for the ''Operating Outlier Payment Reported on the FY 2019 Cost Report'' (Step 2b–;1) we used operating outlier payments reported on Worksheet E, Part A, Lines 2.02, 2.03, and 2.04 from the FY 2019 cost report using the most recent publicly available quarterly HCRIS extract for this proposed rule (that is, the December 2023 HCRIS extract). We propose to move this forward each year and use the most recent publicly available quarterly HCRIS extract (for example, for FY 2026, we would use operating outlier payments reported on Worksheet E, Part A, Lines 2.02, 2.03, and 2.04 from the FY 2020 cost reports using the most recent publicly available quarterly HCRIS extract).
- For the hospitals identified in Step 1b, we have posted a public use file that includes the operating CCR calculated from the FY 2019 cost report in the most recent publicly available quarterly HCRIS extract (the December 2023 HCRIS for this proposed rule), the weighted operating CCR used for claim payment during the FY 2019 cost reporting period from the latest quarterly PSF update (December 2023 for this proposed rule), supplemental data from the MACs and operating outlier payment reported on the FY 2019 cost report.

Step 3.—Calculate the aggregate amount of total Federal operating payments across all applicable hospitals using the Federal FY 2019 cost reports. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Lines 2.02, 2.03, and 2.04), and the outlier reconciliation amounts from Steps 2a and 2b. We note that a negative amount on Worksheet E, Part A, Line 2.01 from Step 2a for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital. Similarly, a negative amount from Step 2b for outlier reconciliation indicates an amount that would have been owed by the hospital, and a positive amount indicates an amount that would have been paid to the hospital.

Step 4.—Divide the aggregate amount from Step 2 (that is, the sum of the amounts from Steps 2a and 2b) by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2019. For FY 2025, the proposed ratio is a negative 0.03979 percent ((−$34,513,755/$86,740,955,496) × 100), which, when rounded to the second digit, is −0.04 percent. This percentage amount would be used to adjust the outlier target for FY 2025 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2019 cost reports, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2025 under our proposed methodology. Therefore, for FY 2025, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (−0.04 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2025 outlier threshold as calculated for this proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the proposed operating outlier offset to the standardized amount was 0.949 (1 − 0.051).

We are inviting public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2025.

(b) Proposed Reduction to the FY 2025 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2025 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2025, we are proposing to continue to use the methodology from FY 2020 to adjust the FY 2025 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers, with modifications to reflect the expansion of outlier reconciliations under the new criteria in CR 13566 (described previously).

For purposes of the methodology for incorporating a projection of capital outlier reconciliations for the FY 2025 outlier adjustment to the capital standard Federal rate to reflect additional cost reports that would be identified for reconciliation under the criteria added by CR 13566, as we discussed in section II.A.4.i.1.a. of the Addendum of this proposed rule regarding the projection of the operating outlier reconciliation, we are not proposing to include the first cost reporting periods of new hospitals because the lack of predictability of new hospitals' data may impact the reliability of our projection. As noted, we expect the proposed modifications to our methodology for incorporating a projection of capital outlier reconciliations into the outlier adjustment to the capital standard federal rate would be necessary for 6 years, at which point the additional FY 2025 cost reports with outlier payments reconciled under the new criteria will be reflected in the HCRIS data available to be used to determine this adjustment.

For FY 2019 hospital cost reports that were reconciled using the original criteria for referral for outlier reconciliation, for this FY 2025 proposed rule, we used the December 2023 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2025 final rule, we propose to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2025, would be the March 2024 extract. As discussed in the FY 2024 IPPS/LTCH final rule (88 FR 59347), we generally expect historical cost reports for the applicable fiscal year to be available by March, and we have worked with our MACs so that historical cost reports for the applicable fiscal year can be made available with the March HCRIS update for the final rule.

To account for the additional hospital cost reports that would be reconciled as a result of the new criteria, we are proposing to use data from the PSF and the cost report to identify the FY 2019 cost reports that would have met the new criteria if those criteria had been in effect. This is because the FY 2019 cost reports in HCRIS would not have been identified as meeting the new criteria for outlier reconciliation since those new criteria are not being used until cost reports beginning with FY 2025. As such, these FY 2019 cost reports do not have an amount reported for operating or capital outlier reconciliation dollars. Therefore, we are proposing to modify our methodology to estimate the outlier reconciliation dollars based on the operating and capital outlier amounts reported on the FY 2019 cost reports and supplemental data collected from the MACs as described further in this section.

Similar to FY 2020, as part of our proposal for FY 2025 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also are proposing to adjust our estimate of FY 2025 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the capital outlier payment adjustment factor). To do so, we are proposing to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2025 outlier threshold calculation, including updated data for FY 2025 and additional steps to reflect the cost reports that would be identified with new criteria under the updated instructions.

Step 1.—Identify hospital cost reports that meet the original criteria or the new criteria.

Step 1a.—Identify hospitals that report on their cost report the capital outlier reconciliation dollars on Worksheet E, Part A, Line 93, Column 1. We note, these were hospitals that were identified by the MACs that met the original criteria for outlier reconciliation and were approved by CMS for outlier reconciliation. We use the Federal FY 2019 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 1b.—For hospitals that were not included in Step 1a, to identify hospitals that would be referred for outlier reconciliation under the new criteria, we used the same hospitals that were identified in Step 1b of the operating methodology. We note, as discussed previously, the new criteria from CR 13566 is based on the change to the operating CCR (not the capital CCR) where the actual operating CCR for the cost reporting period fluctuates plus or minus 20 percent or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed and the hospital had total operating and capital outlier payments greater than $500,000 during the cost reporting period.

Step 2.—Determine the aggregate amount of capital outlier reconciliation dollars (under both the original criteria and the new criteria).

Step 2a.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2019 cost reports from Step 1.

Step 2b.—For the hospitals that would have met the new criteria as identified in Step 1b, to determine the aggregate amount of capital outlier reconciliation dollars, we propose to use the following process (we note this process is the same as Step 2b of the operating methodology):

We collected supplemental estimated outlier payment data from the MACs for claims with discharges occurring during the hospital's FY 2019 cost reporting period to estimate the change in the hospital's outlier payments. Specifically, for each hospital identified in Step 1b, the MACs used the actual capital CCR calculated from the FY 2019 cost report and the utility in the claims system along with that CCR to determine total outlier payments for claims with discharges occurring during the hospital's FY 2019 cost report (this is the same process MACs would have used if the cost report had been identified for reconciliation had the new criteria been in place for FY 2019 cost reports). For those same claims with discharges occurring during the hospital's 2019 cost report, the MAC provided to CMS the outlier payment as reported on the claim (which was based on the hospital's CCR in the PSF at the time of claim payment).

Using this supplemental estimated outlier payment data, we computed a ratio of the outlier payments based on the actual capital CCR for the FY 2019 cost reporting period and the capital CCR used at the time of claim payment. This ratio is then applied to the capital outlier payment reported on the FY

2019 cost report to impute a capital outlier payment for the FY 2019 cost report. We believe it is appropriate to impute the capital outlier payment for the cost report using the supplemental data from the MACs described previously rather than use the actual amount reported on the cost report because the claims data in the claims processing system may slightly differ from the cost report data in the HCRIS due to timing. This approach would also allow CMS to use more recent data (from the most recent publicly available quarterly HCRIS extract, which is December 2023 for this proposed rule) to estimate outlier reconciliation dollars as compared to estimating outlier reconciliation dollars using the supplemental data from the MACs which was submitted by the MACs to CMS beginning in November 2022 (as described in this section). This is also the same data used to determine the aggregate amount of capital outlier reconciliation dollars for hospitals from the FY 2019 cost report data using the December 2023 HCRIS extract in Step 2a.

As presented in the table that follows, to calculate the imputed capital outlier payment for the FY 2019 cost report, we multiplied the capital outlier payment reported on the FY 2019 cost report by the following ratio (determined from the supplemental data collected from the MACs described previously): Capital Outlier Payments from MAC using the CCR from FY 2019 Cost Report divided by Capital Outlier Payments from MAC Based on Claim Payment. The general formula is the following: Capital Outlier Payments Reported on the Cost Report * (Capital Outlier Payments from MAC Using CCRs from FY 2019 Cost Report/ Capital Outlier Payments from MAC Based on Claim Payment).

To calculate the Estimated Capital Outlier Reconciliation Dollars, we then subtracted the Imputed Capital Outlier Amount for the FY 2019 Cost Report (Step 2b–5) from the Capital Outlier Payment Reported on the FY 2019 Cost Report (Step 2b–1).

The following is an example to illustrate our proposed calculation to determine the estimated amount of capital outlier reconciliation dollars for the hospitals that would have met the new criteria:

	Description	Amount
Step 2b-1	Capital Outlier Payment Reported on the FY 2019 Cost Report	$1,000,000
Step 2b-2	Capital Outlier Payments from MAC Using CCRs from the FY 2019 Cost Report	$800,000
Step 2b-3	Capital Outlier Payments from MAC Based on Claim Payment	$975,000
Step 2b-4	Ratio of Step 2b-2 Divided by Step 2b-3	0.82
Step 2b-5	Imputed Capital Outlier Payment for the FY 2019 Cost Report (Step 2b-1 * Step 2b-4)	$820,513
Step 2b-6	Estimated Capital Outlier Reconciliation Dollars (Step 2b-1 - Step 2b-5)	$179,487

We note the following, with regard to the data used in the calculation:

- Due to system limitations the MACs needed 13 months to process all providers' claims through the claims utility (for Steps 2b-2 and 2b-3). The MACs used the operating and capital CCR from the FY 2019 cost reports based on the September 2022 HCRIS extract and began processing the supplemental data for FY 2019 outlier payments in November 2022. We propose to move this forward each year, using the September HCRIS for future fiscal years for the CCRs (for example, for FY 2026, MACs would use CCRs from the 2020 cost reports based on the September 2023 HCRIS).
- For FY 2025, for the ''Capital Outlier Payment Reported on the FY 2019 Cost Report'' (Step 2b-1) we used capital outlier payments reported on Worksheet L, Part I, Line 2 and Line 2.01 from the FY 2019 cost report using the most recent publicly available quarterly HCRIS extract for this proposed rule (that is, the December 2023 HCRIS extract). We propose to move this forward each year and use the most recent publicly available quarterly HCRIS extract (for example, for FY 2026, we would use operating capital payments reported on Worksheet L, Part I, Line 2 and Line 2.01 from the FY 2020 cost reports using the most recent publicly available quarterly HCRIS extract).
- For the hospitals identified in Step 1b, we have posted a public use file that includes the operating CCR calculated from the FY 2019 cost report in the most recent publicly available quarterly HCRIS extract (the December 2023 HCRIS for this proposed rule), the weighted operating CCR used for claim payment during the FY 2019 cost reporting period from the latest quarterly PSF update (December 2023 for this proposed rule), supplemental data from the MACs and capital outlier payments reported on the FY 2019 cost report.

Step 3.—Calculate the aggregate amount of total capital Federal payments across all applicable hospitals using the Federal FY 2019 cost reports. The total capital Federal payments consist of the capital DRG payments, including capital outlier payments, capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation amounts from Steps 2a and 2b. We note that a negative amount on Worksheet E, Part A, Line 93 from Step 2a for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital. Similarly, a negative amount from Step 2b for capital outlier reconciliation indicates an amount that would have been owed by the hospital, and a positive amount indicates an amount that would have been paid to the hospital.

Step 4.—Divide the aggregate amount from Step 2 (that is, the sum of the amounts from Steps 2a and 2b) by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2019. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2025 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we are proposing that the estimate of capital outlier payments for FY 2025 would be determined by adding the percentage in Step 5 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 5 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) We note, when the aggregate capital outlier reconciliation dollars from Steps 2a and 2b are negative, the estimate of capital outlier payments for FY 2025 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

For this FY 2025 proposed rule, the estimated percentage of FY 2025 capital outlier payments otherwise determined using the shared outlier threshold is 4.26 percent (estimated capital outlier payments of $290,612,698 divided by (estimated capital outlier payments of $290,612,698 plus the estimated total capital Federal payment of

$6,532,600,813)). The proposed ratio in Step 5 is a negative −0.026446 percent ((−$2,056,344/$7,775,606,401) × 100), which, when rounded to the second digit, is −0.03 percent. Therefore, for this FY 2025 proposed rule, taking into account projected capital outlier reconciliation under our proposed methodology would decrease the estimated percentage of FY 2025 aggregate capital outlier payments by 0.03 percent.

As discussed in section III.A.2. of this Addendum, we are proposing to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2025.

We are inviting public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2025 capital outlier payments for purposes of determining the capital outlier adjustment factor.

(2) Proposed FY 2025 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2025 outlier threshold, we simulated payments by applying proposed FY 2025 payment rates and policies using cases from the FY 2023 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the Provider-Specific File (PSF) while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2025 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2023 to FY 2025. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are proposing to use the following methodology to calculate the charge inflation factor for FY 2025:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs and REHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).
- Because this payment simulation uses the proposed FY 2025 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this final rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For the same reasons discussed in that rulemaking, for FY 2025, we are proposing to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2025, we are proposing to use the MedPAR files for the two most recent available Federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for this proposed rule we used the December 2022 MedPAR file of FY 2022 (October 1, 2021 to September 30, 2022) charge data (released for the FY 2024 IPPS/LTCH PPS proposed rule) and the December 2023 MedPAR file of FY 2023 (October 1, 2022 to September 30, 2023) charge data (released for this FY 2025 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We are proposing that for the FY 2025 final rule, we would use more recently updated data, that is the MedPAR files from March 2023 for the FY 2022 time period and March 2024 for the FY 2023 time period.

For FY 2025, under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $82,570.13 ($574,544,024,043/6,958,255) from October 1, 2021 through September 30, 2022, to the average covered charge per case of $85,990.03 ($593,444,028,889/6,901,312) from October 1, 2022 through September 30, 2023. This rate-of-change was 4.142 percent (1.04142) or 8.4555 percent (1.084555) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in this FY 2025 IPPS/LTCH PPS proposed rule, we are proposing to establish the FY 2025 outlier threshold using hospital CCRs from the December 2023 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2025, we are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also are proposing that, if more recent data become available, we would use that data to calculate the final FY 2025 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new

methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done in the past, we are proposing to adjust the CCRs from the December 2023 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2022 update of the PSF to the national average case weighted operating CCR and capital CCR from the December 2023 update of the PSF. We note that we used total transfer-adjusted cases from FY 2023 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for this proposed rule, we calculated a December 2022 operating national average case-weighted CCR of 0.246416 and a December 2023 operating national average case-weighted CCR of 0.254624. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2022 operating national average case-weighted CCR from the December 2023 operating national average case-weighted CCR and then dividing the result by the December 2022 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 1.03331.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2022 capital national average case-weighted CCR of 0.018005 and a December 2023 capital national average case-weighted CCR of 0.017765. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2022 capital national average case-weighted CCR from the December 2023 capital national average case-weighted CCR and then dividing the result by the December 2022 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.98667.

For purposes of estimating the proposed outlier threshold for FY 2025, we used a wage index that reflects the policies discussed in this proposed rule. This includes the following:

- Application of the proposed rural and imputed floor adjustment.
- The proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.
- Incorporating the proposed FY 2025 low wage index hospital policy (described in section III.G.5 of the preamble of this proposed rule) for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals.
- Incorporating our policy (described in section III.6. of the preamble of this proposed rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

If we did not take the aforementioned into account, our estimate of total FY 2025 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2025, we are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally.

Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2025, we are proposing to include estimated FY 2025 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, consistent with the methodology finalized in the FY 2023 final rule, we are proposing to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the FY 2025 proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2025 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2025 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.039789 percent, which, when rounded to the second digit, is −0.04 percent. Therefore, for FY 2025, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent −(−.04 percent)]. Under this proposed approach, we determined a proposed threshold of $49,237 and calculated total outlier payments of $4,330,371,122 and total operating Federal payments of $79,917,085,666. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.14 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying

our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $49,601. We are proposing an outlier fixed-loss cost threshold for FY 2025 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $49,237.

(3) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2025 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 4.23 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2025 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2025 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.957708

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2025 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III.A.2 in this Addendum.

We are proposing to apply the outlier adjustment factors to the FY 2025 payment rates after removing the effects of the FY 2024 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.288 or capital CCRs greater than 0.129 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2024 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2025 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2023 Outlier Payments

Our current estimate, using available FY 2023 claims data, is that actual outlier payments for FY 2023 were approximately 5.23 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2023, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2023. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2023 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2024 period would not be available until after September 30, 2024, we are unable to provide an estimate of actual outlier payments for FY 2024 based on FY 2024 claims data in this proposed rule. We will provide an estimate of actual FY 2024 outlier payments in the FY 2026 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2025 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all

hospitals, except hospitals located in Puerto Rico, for FY 2025. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2025.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2025 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2024 national standardized amounts to the proposed FY 2025 national standardized amounts. The second through fifth columns display the changes from the FY 2024 standardized amounts for each proposed applicable FY 2025 standardized amount. The first row of the table shows the updated (through FY 2024) average standardized amount after restoring the FY 2024 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and wage index cap policy budget neutrality. The MS–DRG reclassification and recalibration wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2024 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2025 we have applied the proposed budget neutrality factors for the lowest quartile hospital policy, described previously.

CHANGES FROM FY 2024 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2025 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2025 Base Rate after removing: 1. FY 2024 Geographic Reclassification Budget Neutrality (0.971295) 2. FY 2024 Operating Outlier Offset (0.949)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,782.01 Nonlabor (32.4%): $ 2,291.97	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41
3. FY 2024 Rural Demonstration Budget Neutrality Factor (0.999463) 4. FY 2024 Lowest Quartile Budget Neutrality Factor (0.997402) 5. FY 2024 Cap Policy Wage Index Budget Neutrality Factor (0.999645)	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,385.87 Nonlabor (38%): $2,688.11	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,385.87 Nonlabor (38%): $2,688.11	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,385.87 Nonlabor (38%): $2,688.11	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,385.87 Nonlabor (38%): $2,688.11
Proposed FY 2025 Update Factor	1.026	1.0035	1.0185	0.996
Proposed FY 2025 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	0.997055	0.997055	0.997055	0.997055
Proposed FY 2025 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999617	0.999617	0.999617	0.999617
Proposed FY 2025 Wage Index Budget Neutrality Factor	0.999957	0.999957	0.999957	0.999957
Proposed FY 2025 Reclassification Budget Neutrality Factor	0.976773	0.976773	0.976773	0.976773
Proposed FY 2025 Lowest Quartile Budget Neutrality Factor	0.997498	0.997498	0.997498	0.997498
Proposed FY 2025 Cap Policy Wage Index Budget Neutrality Factor	0.997162	0.997162	0.997162	0.997162
Proposed FY 2025 RCH Demonstration Budget Neutrality Factor	0.999513	0.999513	0.999513	0.999513
Proposed FY 2025 Operating Outlier Factor	0.949	0.949	0.949	0.949
Proposed National Standardized Amount for FY 2025 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,506.29 Nonlabor: $2,159.81**	**Labor: $4,407.47 Nonlabor: $2,112.45**	**Labor: $4,473.35 Nonlabor: $2,144.02**	**Labor: $4,374.53 Nonlabor: $2,096.66**
Proposed National Standardized Amount for FY 2025 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $4,132.98 Nonlabor: $2,533.12**	**Labor: $4,042.35 Nonlabor: $2,477.57**	**Labor: $4,102.77 Nonlabor: $2,514.60**	**Labor: $4,012.14 Nonlabor: $2,459.05**

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2025. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2025, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss

the data and methodology for the FY 2025 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher non-labor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). For FY 2022, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are continuing to use the same COLA factors in FY 2025 that were used in FY 2024 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the COLA factors for FY 2025.

FY 2025 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2022 through FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we intend to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket.

C. Calculation of the Proposed Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2025

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2025 equals the Federal rate (which includes uncompensated care payments). As previously discussed, section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), enacted on December 29, 2022, extended the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024). Subsequently, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, further extended the MDH program for discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Under current law, the MDH program will expire for discharges on or after January 1, 2025.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (which, as discussed in section IVE. of the preamble of this proposed rule, includes uncompensated care payments).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2025 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2025 discharges occurring before January 1, 2025 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim primarily based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount

× Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs – Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment and supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments, supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987, or FY 2002 costs per discharge. As noted, under current law, the MDH program is effective for FY 2025 discharges on or before December 31, 2024.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2025

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.F. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.E.2.d. of the preamble this proposed rule and previously, we are applying a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as finalized in the FY 2023 IPPS/LTCH PPS final rule. Because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900 and 49432 through 49433), the

hospital specific-rate for an SCH or MDH would be adjusted by the proposed MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2024.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2025

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2025, which would be effective for discharges occurring on or after October 1, 2024.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2025

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2025. In particular, we explain why the proposed FY 2025 capital Federal rate would increase approximately 2.50 percent, compared to the FY 2024 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 2.4 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2025 under that framework is 3.0 percent based on a projected 2.5 percent increase in the 2018-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.5 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2025 CIPI projection in that same section of this Addendum. In this proposed rule, we describe the policy adjustments that we are proposing to apply in the update framework for FY 2025.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2025, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2025. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2025 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this proposed rule, we have the FY 2023 MedPAR claims data available to evaluate the effects of the FY 2023 DRG reclassification and recalibration as part of our update for FY 2025. We assume for purposes of this adjustment, that the estimate of FY 2023 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2025.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.5 percentage point was calculated for the FY 2023 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2023 CIPI increase (2.5 percent) used in calculating the FY 2023 update factor is 0.5 percentage point lower than actual realized price increases (3.0 percent). As this exceeds the 0.25 percentage point threshold, we are proposing an adjustment of 0.5 percentage point for the FY 2023 forecast error in the update for FY 2025.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and

data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2025 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2025, we are proposing to use an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2018 and extending through FY 2022. Based on these data, we estimated that case-mix constant intensity declined during FYs 2018 through 2022. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2025. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2025.

Earlier, we described the basis of the components we used to develop the proposed 3.0 percent capital update factor under the capital update framework for FY 2025, as shown in the following table.

PROPOSED FY 2025 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-0.5
Real Across DRG Change	0.5
Subtotal	0.0
Effect of FY 2023 Reclassification and Recalibration	0.0
Forecast Error Correction	0.5
Total Update	3.0

*The capital input price index represents the 2018-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2025, we are proposing to continue to incorporate the impact of estimated operating outlier reconciliation payment amounts into the outlier threshold model. (For more details on our proposal to incorporate an estimate of the impact of operating outlier reconciliation payment amounts into the outlier threshold model, including modifications we are proposing to our methodology to reflect the estimate of operating outlier reconciliation payment amounts under the new criteria which expands the scope of cost reports identified for outlier reconciliation approval in FY 2025, see section II.A.4.i. of this Addendum to this proposed rule.)

For FY 2024, we estimated that outlier payments for capital-related PPS payments would equal 4.02 percent of inpatient capital-related payments based on the capital Federal rate. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 4.26 percent of inpatient capital-related payments based on the proposed capital Federal rate in FY 2025. Using the proposed methodology outlined in section II.A.4.i. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease the estimated percentage of FY 2025 capital outlier payments by 0.03 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 4.23 percent (4.26 percent − 0.03 percent) of inpatient capital-related payments based on the proposed capital Federal rate in FY 2025. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9577 in determining the capital Federal rate for FY 2025. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2025 would be higher than the percentage we estimated for FY 2024. (For more details on our proposed methodology for incorporating the impact of estimated capital outlier reconciliation payment amounts into the calculation of the capital outlier adjustment factor for FY 2025, including modifications we are proposing to make to our methodology to reflect the estimate of capital outlier reconciliation payment amounts under the new criteria which expands the scope of cost reports identified for outlier reconciliation approval in FY 2025, see section II.A.4.i. of this Addendum to this proposed rule.)

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2025 outlier adjustment of 0.9577 is a −0.21 percent change from the FY 2024 outlier adjustment of 0.9598. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2024 is 0.9979 (0.9577/0.9598) so that the proposed outlier adjustment would decrease the FY 2025 capital Federal rate by approximately −0.21 percent compared to the FY 2024 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.5. of the preamble of this proposed rule, in the FY

2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy would be effective for at least 4 years, beginning in FY 2020. This policy was applied in FYs 2020 through 2024, and we are proposing to continue to apply this policy for at least 3 more years, beginning in FY 2025. In addition, beginning in FY 2023, we finalized a permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY regardless of the circumstances causing the decline. That is, under this policy, a hospital's wage index value would not be less than 95 percent of its prior year value (87 FR 49018 through 49021).

We have established a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. In the first step, we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index, which we are proposing to continue in FY 2025, and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section, we refer to the policy that we applied in FYs 2020 through FY 2024 and are proposing to continue to apply in FY 2025, of increasing the wage index for hospitals with a wage index value below the 25th percentile wage index, as the lowest quartile hospital wage index adjustment (also known as low wage index hospital policy). We refer to our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year as the 5-percent cap on wage index decreases policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. However, the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy is not permanently built into the capital Federal rate. This is because the GAFs with the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the proposed GAF budget neutrality factors for FY 2025, we removed from the capital Federal rate the budget neutrality factor applied in FY 2024 for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. Specifically, we divided the capital Federal rate by the FY 2024 budget neutrality factor of 0.9964 (88 FR 59362). We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing the prior year budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases from the capital Federal rate.

In light of the proposed changes to the wage index and other proposed wage index policies for FY 2025 discussed previously, which directly affect the GAF, we are proposing to continue to compute a budget neutrality adjustment for changes in the GAFs in two steps. We discuss our proposed 2-step calculation of the proposed GAF budget neutrality factors for FY 2025 as follows.

To determine the GAF budget neutrality factors for FY 2025, we first compared estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights and the FY 2024 GAFs to estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights and the proposed FY 2025 GAFs without incorporating the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0029 for FY 2025. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2025 GAFs with and without the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2025 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the proposed FY 2025 GAFs (both with and without the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy). (We note, for this calculation the proposed GAFs included the imputed floor, out-migration, and Frontier State adjustments.) To achieve budget neutrality for the effects of the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the proposed FY 2025 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9943. As discussed earlier in this section, the budget neutrality factor for the lowest quartile hospital wage index adjustment factor and the 5-percent cap on wage index decreases policy is not permanently built into the capital Federal rate. Consistent with this, we present the proposed budget neutrality factor for the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy calculated under the second step of this 2-step methodology separately from the other proposed budget neutrality factors in the discussion that follows, and this proposed factor is not included in the calculation of the proposed combined GAF/DRG adjustment factor described later in this section.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. Consistent with our historical methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we finalized to apply an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner (87 FR 49436). Specifically, we augmented our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS–DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS–DRG relative weight decreases.

To determine the proposed DRG budget neutrality factors for FY 2025, we first compared estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the proposed FY 2025 MS–DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2025 GAFs without the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The proposed incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 0.9969. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2025 MS–DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the proposed FY 2025 MS–DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the proposed FY 2025 GAFs without the proposed lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The proposed incremental adjustment factor for the application of the 10-percent cap on relative weight decreases is 0.9996. Therefore, to achieve budget neutrality for the proposed FY 2025 MS–DRG reclassification and recalibration (including

the 10-percent cap), based on the calculations described previously, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9965 (0.9969 × 0.9996) for FY 2025 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The proposed incremental adjustment factor for the proposed FY 2025 MS–DRG reclassification and recalibration (0.9965) and for proposed changes in the FY 2025 GAFs due to the proposed update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0029) is 0.9994 (0.9965 × 1.0029). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the proposal to continue the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2025 GAFs, as described previously, we calculated a proposed budget neutrality adjustment factor of 0.9943 for FY 2025. We refer to this budget neutrality factor for the remainder of this section as the lowest quartile/cap adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the proposed continuation of the lowest quartile hospital wage index adjustment, or the 5-percent cap on wage index decreases policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 0.9994 accounts for the proposed MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for proposed changes in the GAFs that result from proposed updates to the wage data, the effects on the GAFs of FY 2025 geographic reclassification decisions made by the MGCRB compared to FY 2024 decisions, and the application of the rural floor policy. The proposed lowest quartile/cap adjustment factor of 0.9943 accounts for changes in the GAFs that result from our proposal to continue the policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2025

For FY 2024, we established a capital Federal rate of $503.83 (88 FR 59363). We are proposing to establish an update of 3.0 percent in determining the FY 2025 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $516.41 for FY 2025. The proposed national capital Federal rate for FY 2025 was calculated as follows:

- The proposed FY 2025 update factor is 1.03; that is, the proposed update is 3.0 percent.
- The proposed FY 2025 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and proposed changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 0.9994.
- The proposed FY 2025 lowest quartile/cap budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the GAFs that result from our proposal to continue to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy is 0.9943.
- The proposed FY 2025 outlier adjustment factor is 0.9577.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2025 affects the computation of the proposed FY 2025 national capital Federal rate in comparison to the FY 2024 national capital Federal rate. The proposed FY 2025 update factor has the effect of increasing the capital Federal rate by 3.0 percent compared to the FY 2024 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.06 percent. The proposed FY 2025 lowest quartile/cap budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.21 percent compared to the FY 2024 capital Federal rate. The proposed FY 2025 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.21 percent compared to the FY 2024 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 2.5 percent, compared to the FY 2024 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2024 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2025 CAPITAL FEDERAL RATE

	FY 2024	Proposed FY 2025	Change	Percent Change
Update Factor[1]	1.0380	1.0300	1.0300	3.00
GAF/DRG Adjustment Factor[1]	0.9885	0.9994	0.9994	-0.06
Quartile/Cap Adjustment Factor[2]	0.9964	0.9943	0.9979	-0.21
Outlier Adjustment Factor[3]	0.9598	0.9577	0.9979	-0.21
Capital Federal Rate	$503.83	$516.41	1.0250	2.50[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2024 to FY 2025 resulting from the application of the proposed 0.9994 GAF/DRG budget neutrality adjustment factor for FY 2025 is a net change of 0.9994 (or -0.06 percent).

[2] The lowest quartile/cap budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2025 lowest quartile/cap budget neutrality adjustment factor is 0.9943/0.9964 or 0.9979 (or -0.21 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2025 outlier adjustment factor is 0.9577/0.9598 or 0.9979 (or -0.21 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2025

For purposes of calculating payments for each discharge during FY 2025, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2025 is in section II.A. of this Addendum. For FY 2025, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus the proposed fixed-loss amount of $49,237.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

For this proposed rule, we are proposing to use the IPPS operating and capital market baskets that reflect a 2018 base year. For a complete discussion of the 2018-based market baskets, we refer readers to section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45213).

2. Forecast of the CIPI for FY 2025

Based on IHS Global Inc.'s (IGI) fourth quarter 2023 forecast, for this proposed rule, we are forecasting the 2018-based CIPI to increase 2.5 percent in FY 2025. This reflects a projected 3.0 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.9 percent increase in other capital expense prices in FY 2025, partially offset by a projected 1.1 percent decline in vintage-weighted interest expense prices in FY 2025. The weighted average of these three factors produces the forecasted 2.5 percent increase for the 2018-based CIPI in FY 2025.

We are also proposing that if more recent data become available (for example, a more recent estimate of the percentage increase in the 2018-based CIPI), we would use such data, if appropriate, to determine the FY 2025 percentage increase in the 2018-based CIPI for the final rule.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2025

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are paid on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For this FY 2025 IPPS/LTCH PPS proposed rule, based on IGI's 2023 fourth quarter forecast, we estimate that the 2018-based IPPS operating market basket rate-of-increase for FY 2025 is 3.0 percent. Based on this estimate, the proposed FY 2025 rate-of-increase percentage that will be applied to the FY 2024 target amounts in order to calculate the proposed FY 2025 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals will be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket rate-of-increase, we would use such data, if appropriate, to calculate the final IPPS operating market basket rate-of-increase for FY 2025.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble and section V. of the Addendum of this proposed rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2025. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2025

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2025

1. Overview

In section VIII. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2025.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section VIII.C.2. of the preamble of this proposed rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2025 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2025, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2025,

we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2025 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.6. of this Addendum.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.8 percent (that is, the most recent estimate of the proposed 2022-based LTCH market basket increase of 3.2 percent less the proposed productivity adjustment of 0.4 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply an update factor of 1.028 to the FY 2024 LTCH PPS standard Federal payment rate of $48,116.62 to determine the proposed FY 2025 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2025 as required under the LTCH QRP. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.8 percent (or an update factor of 1.008). This proposed update reflects the proposed annual market basket update of 3.2 percent reduced by the proposed 0.4 percentage point productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act, minus 2.0 percentage points for LTCHs failing to submit quality data under the LTCH QRP, as required by section 1886(m)(5) of the Act. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2025 LTCH PPS standard Federal payment rate of 0.9959347, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index (including the proposed update to the CBSA labor market areas and the application of the 5-percent cap on wage index decreases, discussed later in this section), and proposed labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $49,262.80 (calculated as $48,116.62 × 1.028 × 0.9959347) for FY 2025. For LTCHs that fail to submit quality reporting data for FY 2025, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $48,304.38 (calculated as $48,116.62 × 1.008 × 0.9959347) for FY 2025.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2025

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2025 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2024, through September 30, 2025, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of this Addendum and available via the internet on the CMS website.

2. Proposed Geographic Classifications (Labor Market Areas) Under the LTCH PPS

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf*.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded OMB Bulletin No. 17–01 (August 15, 2017). On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded OMB Bulletin No. 18–03 (April 10, 2018). Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, OMB Bulletin No. 18–04 (September 14, 2018) included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of OMB Bulletin No. 18–04 (September 14, 2018) may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*.) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area. After reviewing OMB Bulletin No. 20–01, we determined that the changes in OMB Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Therefore, we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45556 through 45557) consistent with our general policy of adopting OMB delineation updates;

however, the LTCH PPS area wage level adjustment was not altered as a result of adopting the updates because the CBSA-based labor market area delineations were the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR59050 through 59051). Thus, most recently in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59366), we continued to use the CBSA-based labor market area delineations as established in OMB Bulletin 18–04 and OMB Bulletin 20–01.

In the July 16, 2021 **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01, which superseded OMB Bulletin No. 20–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). In this proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to adopt the revised delineations announced in OMB Bulletin No. 23–01 effective for FY 2025 under the LTCH PPS. We believe that adopting the CBSA-based labor market area delineations established in OMB Bulletin 23–01 would ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). This proposal to adopt the revised delineations announced in OMB Bulletin No. 23–01 is consistent with the changes proposed under the IPPS for FY 2025 as discussed in section III.B. of the preamble of this proposed rule. A summary of these proposed changes is presented in the discussion that follows in this section. For complete details on the proposed changes, we refer readers to section III.B. of the preamble of this proposed rule.

a. Urban Counties That Would Become Rural Under the Revised OMB Delineations

CBSAs are made up of one or more constituent counties. Analysis of the revised labor market area delineations (based upon OMB Bulletin No. 23–01) that we propose to implement, beginning in FY 2025, shows that a total of 53 counties (and county equivalents) that were located in an urban CBSA pursuant to OMB Bulletin No. 20–01 would be located in a rural area under the revised OMB delineations. The chart in section III.B.4. of the preamble of this proposed rule lists the 53 urban counties that would be rural under these revised OMB delineations.

b. Rural Counties That Would Become Urban Under the Revised OMB Delineations

Analysis of the revised labor market area delineations (based upon OMB Bulletin No. 23–01) that we propose to implement, beginning in FY 2025, shows that a total of 54 counties (and county equivalents) that were located in a rural area pursuant to OMB Bulletin No. 20–01 would be located in an urban CBSA under the revised OMB delineations. The chart in section III.B.5. of the preamble of this proposed rule lists the 54 rural counties that would be urban under these revised OMB delineations.

c. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the revised delineations announced in OMB Bulletin No. 23–01. In other cases, adopting the revised delineations announced in OMB Bulletin No. 23–01 would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 23844 (Gary, IN) would experience both a change to its number and its name and become CBSA 29414 (Lake County-Porter County-Jasper County, IN), while all of its four constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. The chart in section III.B.6. of the preamble of this proposed rule lists the CBSAs where we are proposing to change the name and/or CBSA number only.

There are also counties that would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs, under our proposal to adopt the revisions to the OMB delineations based on OMB Bulletin No. 23–01. For example, some CBSAs would be split into multiple new CBSAs, or a CBSA would lose one or more counties to other urban CBSAs. The chart in section III.B.6 of the preamble of this proposed rule lists the urban counties that would move from one urban CBSA to a new or modified CBSA under our proposal to adopt these revisions to the OMB delineations.

d. Change to County-Equivalents in the State of Connecticut

For FY 2025, we are continuing to use the Federal Information Processing Standard (FIPS) county codes, maintained by the U.S. Census Bureau, for purposes of cross walking counties to CBSAs. In a June 6, 2022 **Federal Register** notice (87 FR 34235 through 34240), the Census Bureau announced that it was implementing the State of Connecticut's request to replace the 8 counties in the State with 9 new ''Planning Regions.'' Planning regions now serve as county-equivalents within the CBSA system. OMB Bulletin No. 23–01 is the first set of revised delineations that referenced the new county-equivalents for Connecticut. We have evaluated the change in hospital assignments for Connecticut LTCHs and are proposing to adopt the planning regions as county equivalents for wage index purposes. As all forthcoming county-based delineation data will utilize these new county-equivalent definitions for the Connecticut, we believe it is necessary to adopt this migration from counties to planning region county-equivalents in order to maintain consistency with OMB Bulletin No. 23–01 and future OMB updates. This proposal to adopt the planning regions as county equivalents for wage index purposes is consistent with the changes proposed under the IPPS for FY 2025 as discussed in section III.B.3. of the preamble of this proposed rule. We are providing the following crosswalk for each LTCH in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

CCN	Current FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
072003	09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
072004	09003	HARTFORD	25540	09110	CAPITOL	25540

As previously discussed, we are proposing to adopt the revisions announced in OMB Bulletin No. 23–01 to the CBSA-based labor market area delineations under the LTCH PPS, effective October 1, 2024. Accordingly, the proposed FY 2025 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website) reflect the proposed revisions to the CBSA-based labor market area delineations previously described. We also are including in a supplemental data file an updated county-to-CBSA crosswalk that reflects the proposed revisions to the CBSA-based labor market area delineations. This supplemental data file for public use will be posted on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

As discussed in section VIII.D of the preamble to this proposed rule, effective for FY 2025, we are proposing to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year. In conjunction with that proposal, as discussed in section VIII.D. of the preamble of this proposed rule, we are also proposing that the LTCH PPS labor-related share for FY 2025 would be the sum of the FY 2025 relative importance of each labor-related cost category in the proposed 2022-based LTCH market basket using the most recent available data. Table VIII.D–09 in section VIII.D. of the preamble of this proposed rule shows the proposed FY 2025 labor-related share using the proposed 2022-based LTCH market basket and the FY 2024 labor-related share using the 2017-based LTCH market basket. The proposed labor-related share for FY 2025 is the sum of the labor-related portion of operating costs from the proposed 2022-based LTCH market basket (that is, the sum of the FY 2025 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) and a portion of the relative importance of Capital-Related cost weight from the proposed 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2025. Based on IHS Global Inc.'s fourth quarter 2023 forecast of the proposed 2022-based LTCH market basket, the sum of the FY 2025 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services was 68.9 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based, 2013-based, and 2017-based LTCH market basket capital-related costs relative importance). Since the FY 2025 relative importance for capital-related costs was 8.4 percent based on IHS Global Inc.'s fourth quarter 2023 forecast of the proposed 2022-based LTCH market basket, we took 46 percent of 8.4 percent to determine the labor-related share of capital-related costs for FY 2025 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2025 of 72.8 percent (the sum of 68.9 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of capital-related costs). The total difference between the FY 2025 labor-related share using the proposed 2022 based LTCH market basket (72.8 percent) and the FY 2024 labor-related share using the 2017 based LTCH market basket (68.5 percent) is 4.3 percentage points. As discussed in greater detail in section VIII.D. of the preamble of this proposed rule, this difference is primarily attributable to the revision to the base year cost weights for those categories included in the labor-related share. Consistent with our historical practice, we are proposing that if more recent data becomes available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the proposed 2022-based LTCH market basket), we will use such data, if appropriate, to determine the FY 2025 LTCH PPS labor-related share.

4. Proposed Wage Index for FY 2025 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2025 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to employ our historical practice of using the same data we used to compute the proposed FY 2025 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2021) because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2025 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2025, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2021 IPPS wage data that we are proposing to use to determine the proposed FY 2025 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the proposed FY 2025 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, proposed CBSAs 10500, 12020, 12054, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 31924, 40660, 42340, 46660, and 47580), as shown in Table 12A, which is listed in section VI. of this Addendum.

Based on the FY 2021 IPPS wage data that we are proposing to use to determine the proposed FY 2025 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for rural North Dakota (CBSA 35). Consistent with our existing methodology, we calculated the proposed FY

2025 wage index value for CBSA 35 as the average of the wage index values for all proposed CBSAs that are contiguous to the rural counties of the State (that is, proposed CBSAs 13900, 22020, 24220, and 33500), as shown in Table 12B, which is listed in section VI. of this Addendum. We note that, as IPPS wage data are dynamic, it is possible that the number of urban and rural areas without IPPS wage data will vary in the future.

5. Permanent Cap on Wage Index Decreases

a. Permanent Cap on LTCH PPS Wage Index Decreases

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49440 through 49442), we finalized a policy that applies a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. Consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we include the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of this Addendum.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. An LTCH's wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2025 would not be eligible for the LTCH PPS wage index cap in FY 2025. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage index cap. The cap on wage index decreases policy is reflected at § 412.525(c)(1).

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

b. Permanent Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information on this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49442 through 49443), we finalized a policy that applies a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

Under this policy, an LTCH's applicable IPPS comparable wage index will not be less than 95 percent of its applicable IPPS comparable wage index for the prior fiscal year. An LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2025 would not be eligible for the applicable IPPS comparable wage index cap in FY 2025. This means that these LTCHs would receive the calculated applicable IPPS comparable wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. The cap on IPPS comparable wage index decreases policy is reflected at § 412.529(d)(4)(ii)(B) and (d)(4)(iii)(B).

Similar to the information we are making available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

6. Proposed Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2025, in accordance with § 412.523(d)(4), we are applying a proposed area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.6. of this Addendum, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the proposed area wage level budget neutrality factor. Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2025 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2024 wage index values and the FY 2024 labor-related share of 68.5 percent. We note that the FY 2024 wage index values are based on the existing CBSA labor market areas used in the FY 2024 IPPS/LTCH PPS final rule.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate

payments using the proposed FY 2025 wage index values (including the proposed update to the CBSA labor market areas and the application of the 5 percent cap on wage index decreases) and the proposed FY 2025 labor-related share of 72.8 percent. (As noted previously, the proposed changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the proposed labor-related share is discussed in section V.B.3. of this Addendum.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2024 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2025 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for updates to the area wage level adjustment for FY 2025 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the proposed FY 2025 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2025 LTCH PPS standard Federal payment rate after the application of the proposed FY 2025 annual update.

We are proposing to use the most recent data available, including claims from the FY 2023 MedPAR file, in calculating the FY 2025 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2025 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed the abnormal charging practices of an LTCH (CCN 312024) in FY 2021 that led to the LTCH receiving an excessive amount of high-cost outlier payments. In that rule, we stated our understanding that, based on information we received from the provider, these abnormal charging practices would not persist into FY 2023. Therefore, we did not include their cases in our model for determining the FY 2023 outlier fixed-loss amount. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59376), we stated that the FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. Therefore, we removed claims from CCN 312024 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 and all other FY 2024 ratesetting calculations, including the MS–LTC–DRG relative weights and the calculation of the area wage level adjustment budget neutrality factor. Given recent actions by the Department of Justice regarding CCN 312024 (see *https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related*), we are proposing to again remove claims from CCN 312024 when determining the area wage level adjustment budget neutrality factor for FY 2025 and all other FY 2025 ratesetting calculations, including the MS–LTC–DRG relative weights and the fixed-loss amount for LTCH PPS standard Federal payment rate cases.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2025 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.9959347. Accordingly, in section V.A. of this Addendum, we applied the proposed area wage level adjustment budget neutrality factor of 0.9959347 to determine the proposed FY 2025 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we have updated the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2022 (86 FR 45559 through 45560).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this proposed rule, for FY 2025, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2022 COLA factors, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS (COLA): ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2025

Area	FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Pub. L. 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and are also used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. Proposed LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the best available data to determine the LTCH total CCR ceiling for FY 2025 in this proposed rule. Specifically, in this proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2023 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are proposing an LTCH total CCR ceiling of 1.371 under the LTCH PPS for FY 2025 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to

determine the LTCH total CCR ceiling for FY 2025 in the final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, we are proposing to use our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2023 update of the PSF. We are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2024, through September 30, 2025, in Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2025 in the final rule.

Under the proposed LTCH PPS labor market areas, all areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

Furthermore, although Connecticut, Massachusetts, Nevada, and North Dakota have areas that are designated as rural under the proposed LTCH PPS labor market areas, in our calculation of the LTCH statewide average CCRs, there were no trimmed CCR data available from IPPS hospitals located in these rural areas as of December 2023. We refer the reader to section II.A.4.i.(2). of this Addendum for details on the trims applied to the IPPS CCR data from the December 2023 update of the PSF, which are the same data used to calculate the LTCH statewide average total CCRs. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut, Massachusetts, Nevada, and North Dakota in Table 8C. We note that there were no LTCHs located in these rural areas as of December 2023.

d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821), and most recently modified by Change Request 13566 (Transmittal 12558; March 28, 2024) with an update to the outlier reconciliation criteria.

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2025

In this section of this Addendum, we discuss our proposed methodology for determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025. As we state later in this section, the proposed fixed-loss amount we determined for FY 2025 is significantly higher than the fixed-loss amount we finalized for FY 2024 (88 FR 59377). As we discuss later in this section, we are soliciting comments on our proposed fixed-loss amount as well as an alternative approach that we considered for determining the fixed-loss amount for FY 2025. We refer the reader to section I.O.4. of Appendix A of this proposed rule for our full discussion on the alternative approach.

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed the abnormal charging practices of an LTCH (CCN 312024) in FY 2021 that led to the LTCH receiving an excessive amount of high-cost outlier payments. In that rule, we stated our belief, based on information we received from the provider, that these abnormal charging practices would not persist into FY 2023. Therefore, we did not include their cases in our model for determining the FY 2023 outlier fixed-loss amount. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59376), we

stated that the FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. Therefore, we removed claims from CCN 312024 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 and all other FY 2024 ratesetting calculations, including the MS–LTC–DRG relative weights and the calculation of the area wage level adjustment budget neutrality factor. Given recent actions by the Department of Justice regarding CCN 312024 (see *https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related*), we are proposing to again remove claims from CCN 312024 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 and all other FY 2025 ratesetting calculations, including the MS–LTC–DRG relative weights and the calculation of the area wage level adjustment budget neutrality factor.

(1) Proposed Charge Inflation Factor for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2025

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor.

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.i.(2). of this Addendum), our methodology determines the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data. In this section of this Addendum, we describe our charge inflation factor methodology.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases

The first step in our methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers

The next step in our methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. Then we remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor

The final step in our methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. Then we calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

Following the methodology described previously, we computed a proposed charge inflation factor based on the most recently available data. Specifically, we used the December 2023 update of the FY 2023 MedPAR file and the December 2022 update of the FY 2022 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. Therefore, we trimmed the December 2023 update of the FY 2023 MedPAR file and the December 2022 update of the FY 2022 MedPAR file as described in steps 1 and 2 of our methodology. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $280,441 ($11,524,447,130/41,094 cases) from FY 2022 to the average covered charge per case of $301,155 ($12,627,438,548/41,930 cases) from FY 2023. This rate-of-change was 7.3863 percent, which results in a 1-year charge inflation factor of 1.073863, and a 2-year charge inflation factor of 1.153182 (calculated by squaring the 1-year factor). We propose to inflate the billed charges obtained from the FY 2023 MedPAR file by this 2-year charge inflation factor of 1.153182 when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025.

(2) CCRs for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2025

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.i.(2). of this Addendum), our methodology adjusts CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case-weighted CCR for LTCHs. We believe these adjusted CCRs more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section of this Addendum, we describe our CCR adjustment factor methodology.

Step 1—Assign Providers Their Historical CCRs

The first step in our methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available one year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data

The next step in our methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers

The next step in our methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate a CCR Adjustment Factor

The final step in our methodology is to calculate, across all remaining providers after application of Step 3, an average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short stay outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Following the methodology described previously, we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the December 2023 PSF as the most recently available PSF

and the December 2022 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our methodology. In addition, we used claims from the December 2023 update of the FY 2023 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. Specifically, following the methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the December 2023 update of the FY 2023 MedPAR file, we identified their CCRs from both the December 2022 PSF and December 2023 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2023 MedPAR file (classified using proposed Version 42 of the GROUPER) to calculate case-weighted average CCRs. Based on this data, we calculated a December 2022 national average case-weighted CCR of 0.232841 and a December 2023 national average case-weighted CCR of 0.238141. We then calculated the proposed national CCR adjustment factor by dividing the December 2023 national average case-weighted CCR by the December 2022 national average case-weighted CCR. This results in a proposed 1-year national CCR adjustment factor of 1.02276. When calculating the proposed fixed-loss amount for FY 2025, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the December 2023 PSF or whose CCR was missing in the December 2023 PSF. For all other providers, we multiplied their CCR from the December 2023 PSF by the proposed 1-year national CCR adjustment factor of 1.02276.

(3) Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2025

In this proposed rule, for FY 2025, using the best available data and the steps described previously, we calculated a proposed fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases as required by section 1886(m)(7) of the Act and in accordance with § 412.525(a)(2)(ii) (based on the proposed payment rates and policies for these cases presented in this proposed rule). Consistent with our historical practice, we are proposing to use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 in the final rule. Therefore, based on LTCH claims data from the December 2023 update of the FY 2023 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2023 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 of $90,921 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2025 payments for such cases. As such, we would make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $90,921).

The proposed fixed-loss amount for FY 2025 ($90,921) is significantly higher than the fixed-loss amount for FY 2024 ($59,873). Each year the fixed-loss amount is determined prospectively based on the best available data at the time. Using the FY 2023 MedPAR file, we estimate that actual high-cost outlier payments accounted for 11.6 percent of total LTCH PPS standard Federal payment rate payments in FY 2023. This percentage is much higher than the budget neutral target of 7.975 percent that we modelled, using the best available data at the time, when determining the FY 2023 fixed-loss amount of $38,518 (87 FR 49449). We currently estimate that for actual high-cost outlier payments to have accounted for 7.975 percent of total LTCH PPS standard Federal payment rate payments in FY 2023, the fixed-loss amount would have needed to have been set at approximately $65,260. Furthermore, as discussed in Appendix A to this proposed rule, we currently model that high-cost outlier payments in FY 2024 will account for 9.3 percent of total LTCH PPS standard Federal payment rate payments. This percentage is also much higher than the budget neutral target of 7.975 percent that we modelled, using the best available data at the time, when determining the FY 2024 fixed-loss amount of $59,873 (88 FR 59377). Based on this model, we estimate that the FY 2024 fixed-loss amount would have needed to have been set at approximately $72,275 to meet the requirement that high-cost outlier payments account for 7.975 percent of total LTCH PPS standard Federal payment rate payments in FY 2024.

Based on this recent experience, we believe a large increase to the fixed-loss amount would be warranted to ensure that estimated outlier payments in FY 2025 return to our statutorily required budget neutral target of 7.975 percent. However, we acknowledge that the proposed increase to the fixed-loss amount is substantial. In section I.O.4. of Appendix A of this proposed rule, we discuss an alternative approach we considered for determining the proposed FY 2025 fixed-loss amount that may have mitigated the magnitude of the increase in the proposed fixed-loss amount for FY 2025. As stated in that section, we are soliciting comments on both our proposed methodology for determining the FY 2025 fixed-loss amount and the alternative approach. We will consider these comments when finalizing the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 in the final rule.

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2024, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases and the provisions of section 3711(b)(2) of the CARES Act, the historical claims data available in each of these years were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2024, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2024 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2024. In particular, in

FY 2024, we established the fixed-loss amount for site neutral payment rate cases as the FY 2024 IPPS fixed-loss amount of $42,750 (88 FR 59378).

For this proposed rule, we used FY 2023 data in the FY 2025 LTCH PPS proposed ratesetting. We note that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, all LTCH PPS cases in FY 2023 with admission dates on or before the PHE expiration date were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Because not all FY 2023 claims in the data used for this proposed rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2024 when developing a fixed-loss amount for site neutral payment rate cases for FY 2025. Our actuaries continue to project that the costs and resource use for FY 2025 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2023 LTCH claims data used in the development of this final rule, if the provisions of the CARES Act had not been in effect, approximately 71 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 29 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2023.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2025 is the IPPS fixed-loss amount for FY 2025. Therefore, for FY 2025, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $49,237, which is the same proposed FY 2025 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of this Addendum. Accordingly, under this policy, for FY 2025, we would calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $49,237).

In establishing an HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2025 would not result in any increase in estimated aggregate FY 2025 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2025. Consistent with our historical practice, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2025 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2025 would not result in any increase in estimated aggregate FY 2025 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2025. To achieve this, for FY 2025, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0—5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments.

To reflect the Medicare DSH payment adjustment methodology statutory changes in section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766) that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated, in the FY 2014 IPPS/LTC PPS final rule (78 FR 50766), that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2025, as discussed in greater detail in section IV.E.2.b. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 62.14 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2025. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 46.61 percent (the product of 75 percent and 62.14 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2025, we project that the reduction in the amount of Medicare

DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 71.61 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 46.61 percent = 71.61 percent).

Therefore, for FY 2025, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 71.61 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2025

Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages; we make this adjustment by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2025 values are shown in Tables 12A through 12B listed in section VI. of this Addendum and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2025 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2025 of $49,262.80, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2025, applying our proposed LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

Example:

During FY 2025, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2025 LTCH PPS wage index value of 1.0237 (as shown in Table 12A listed in section VI. of this Addendum). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2025 of 0.9791 (as shown in Table 11 listed in section VI. of this Addendum). The LTCH submitted quality reporting data for FY 2025 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2025, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2025 LTCH PPS standard Federal payment rate ($49,262.80) by the proposed labor-related share (72.8 percent) and the proposed wage index value (1.0237). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (27.2 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9791) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2025 ($49,065.40). The table illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$49,262.80
Proposed Labor-Related Share	x 0.728
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $35,863.32
Proposed Wage Index (CBSA 16984)	x 1.0237
Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $36,713.28
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($49,262.80 x 0.272)	+ $13,399.48
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $50,112.76
Proposed MS-LTC-DRG 189 Relative Weight	x 0.9791
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $49,065.40

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2024, for the FY 2025 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be on the CMS website. Specifically, all IPPS tables listed in the proposed rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available on the CMS website. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49452), we finalized beginning with FY 2023, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file. The AOR/BOR files can be found on the FY 2025 IPPS proposed rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

After hospitals have been given an opportunity to review and correct their calculations for FY 2025, we will post Table 15 (which will be available via the CMS website) to display the final FY 2025 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2024. We expect Table 15 will be posted on the CMS website in the Fall 2024.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled ''FY 2025 IPPS Proposed Rule Home Page'' or ''Acute Inpatient -Files- for Download.''

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2025 Proposed Rule

Table 3.—Proposed Wage Index Table by CBSA—FY 2025 Proposed Rule

Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2025 Proposed Rule

Table 4B.—Proposed Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2025 Proposed Rule

Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and

Geometric and Arithmetic Mean Length of Stay—FY 2025 Proposed Rule
Table 6A.—New Diagnosis Codes—FY 2025
Table 6B.—New Procedure Codes—FY 2025
Table 6C.—Invalid Diagnosis Codes—FY 2025
Table 6D.—Invalid Procedure Codes—FY 2025
Table 6E.—Revised Diagnosis Code Titles—FY 2025
Table 6F.—Revised Procedure Code Titles—FY 2025
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2025
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2025
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2025
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2025
Table 6I.1.—Proposed Additions to the MCC List—FY 2025
Table 6J.1.—Proposed Additions to the CC List—FY 2025
Table 6J.2.—Proposed Deletions to the CC List—FY 2025
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2025 (Table 6P contains multiple tables, 6P.1a. through 6P.2h that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG changes or other analyses). These tables are referred to throughout section II.C. of the preamble of this proposed rule.
Table 8A.—Proposed FY 2025 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2025 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 16.—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2025
Table 18.—Proposed FY 2025 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2025 proposed rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1808–P:

Table 8C.—Proposed FY 2025 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2024, through September 30, 2025
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2024, through September 30, 2025
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2024, through September 30, 2025

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TABLE 1A.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2025

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,506.29	$2,159.81	$4,407.47	$2,112.45	$4,473.35	$2,144.02	$4,374.53	$2,096.66

TABLE 1B.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2025

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,132.98	$2,533.12	$4,042.35	$2,477.57	$4,102.77	$2,514.60	$4,012.14	$2,459.05

TABLE 1C.— PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2025

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.6)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 0.35)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$4,132.98	$2,533.12	$4,012.14	$2,459.05

[1] For FY 2025, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2025

	Rate
National	$516.41

TABLE 1E.— PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2025

	Full Update (2.8 Percent)	Reduced Update* (0.8 Percent)
Standard Federal Rate	$49,262.80	$48,304.38

* For LTCHs that fail to submit quality reporting data for FY 2025 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Proposed Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section V.B. of the preamble to this proposed rule, we are proposing to update the national standardized amount for inpatient hospital operating costs by the proposed applicable percentage increase of 2.6 percent (that is, a proposed 3.0 percent market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment). We are also proposing to apply the proposed applicable percentage increase (including the market basket update and the proposed productivity adjustment) to the hospital-specific rates.

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive a proposed applicable percentage increase of 1.850 percent which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data. Hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of 0.350 percent which reflects a three-quarter percent reduction of the market basket update for being identified as not a meaningful EHR user.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.4 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for being identified as not a meaningful EHR user.

b. Proposed Changes for the Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, we review applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(f)(1), we consider whether a technology meets the criteria for the new technology add-on payment and announce the results as part of the annual updates and changes to the IPPS. New technology add-on payments are not budget neutral.

As discussed in section II.E.7. of the preamble of this proposed rule, we are

proposing that beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, we would extend new technology add-on payments for an additional fiscal year when the three-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of the upcoming fiscal year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we would continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered ''new'' for purposes of new technology add-on payments. Similarly, we are also proposing that beginning with applications for new technology add-on payments for FY 2026, we would use the start of the fiscal year (October 1) instead of April 1 to determine whether to approve new technology add-on payment for that fiscal year. We note that this proposal, if finalized, would be effective beginning with new technology add-on payments for FY 2026, and there would be no impact of this proposal in FY 2025. We note that it is premature to estimate the potential payment impact for this proposal because we have not yet determined whether any of the FY 2025 new technology add-on payment applications will meet the specified criteria for new technology add-on payments for FY 2025. However, for purposes of estimating the impact of our proposed changes to the calculation of the inpatient new technology add-on payment—if we determine that all 10 of the FY 2025 new technology add-on payment applications that have been FDA-approved or cleared since the start of FY 2024 (as discussed in section II.E.5. and section II.E.6. of the preamble of this proposed rule) meet the specified criteria for new technology add-on payments for FY 2025, FY 2026, and FY 2027, and if we determine that none of these technologies would be substantially similar to those technologies that were first approved for new technology add-on payments prior to FY 2025—based on preliminary information from the applicants at the time of this proposed rule, this proposal, if finalized, would increase IPPS spending by approximately $380 million in FY 2027.

As discussed in section II.E.8. of the preamble of this proposed rule, we are proposing that beginning with new technology add-on payment applications for FY 2026, we would no longer consider a hold status to be an inactive status for the purposes of eligibility for the new technology add-on payment under our existing policy for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application. Under this existing policy, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. We note that the cost impact of this proposal is not estimable. We expect that some applicants who were ineligible to apply in FY 2025 may apply for new technology add-on payments for FY 2026.

As discussed in section II.E.9. of the preamble of this proposed rule, we are proposing that, subject to our review of the new technology add-on payment eligibility criteria, for a gene therapy approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule for the treatment of sickle cell disease (SCD), effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare would make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We note that it is premature to estimate the potential payment impact for FY 2025 because we have not yet determined whether any gene therapy indicated and used specifically for the treatment of SCD will meet the specified criteria for new technology add-on payments for FY 2025.

c. Proposed Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We also stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. As discussed in section III.G.5. of the preamble of this proposed rule, while we are using the FY 2021 cost report data for the FY 2025 wage index, we are unable to comprehensively evaluate the effect, if any, the low wage index hospital policy had on hospitals' wage increases during the years the COVID–19 PHE was in effect. We believe it is necessary to wait until we have useable data from fiscal years after the PHE before reaching any conclusions about the efficacy of the policy. Therefore, we are proposing that the low wage index hospital policy and the related budget neutrality adjustment would be effective for at least 3 more years, beginning in FY 2025.

d. Proposed Implementation of Section 4122 of the Consolidated Appropriations Act, 2023 (CAA, 2023)

As discussed in section V.G.2. of the preamble of this proposed rule, we are we are including a proposal to implement section 4122 of the Consolidated Appropriations Act (CAA) of 2023. Section 4122(a) of the CAA, 2023, amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of additional residency positions (also referred to as slots) to hospitals. Section 4122 makes available 200 residency positions, to be distributed beginning in FY 2026, with priority given to hospital sin 4 statutorily specified categories. At least 100 of the 200 residency positions made available under section 4122 shall be distributed for psychiatry or psychiatry subspecialty residency training programs. We expect these changes will make appropriate Medicare GME payments to hospitals for Medicare's share of the direct costs to operate the hospital's approved medical residency program, and for IPPS hospitals the indirect costs associated with residency programs that may result in higher patient care costs, consistent with the law. We expect that these changes will ensure that the outcomes of these Medicare payment policies are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

e. Additional Payment for Uncompensated Care to Medicare Disproportionate Share Hospitals (DSHs) and Supplemental Payment

In this proposed rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the 3 factors used to determine uncompensated care payments for FY 2025. Beginning with FY 2023, we adopted a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which would help to mitigate against large fluctuations in uncompensated care payments from year to year. Under this methodology, for FY 2025 and subsequent fiscal years, we would determine Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. Specifically, we would use a 3-year average of audited data on uncompensated care costs from Worksheet S–10 from the FY 2019, FY 2020, and FY 2021 cost reports to calculate Factor 3 for FY 2025 for all eligible hospitals.

Beginning with FY 2023 (87 FR 49047 through 49051), we also established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico. In section IV.D. of the preamble of this proposed rule, we summarize the ongoing methodology for supplemental payments.

f. Rural Community Hospital Demonstration Program

The Rural Community Hospital Demonstration (RCHD) was authorized originally for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and it was extended for another 5-year period by section 3123 and 10313 of the Affordable Care Act

(Pub. L. 111–148). Section 15003 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) extended the demonstration for an additional 5-year period, and section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159) included an additional 5-year re-authorization. CMS has conducted the demonstration since 2004, which allows enhanced, cost-based payment for Medicare inpatient services for up to 30 small rural hospitals.

The authorizing legislation imposes a strict budget neutrality requirement. In this proposed rule, we summarize the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–159). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this proposed rule, we propose to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

3. Proposed Update to the LTCH PPS Payment Rates

As discussed in section VIII.D. of the preamble of this proposed rule, we are proposing to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year. The proposed update to the LTCH PPS standard Federal payment rate for FY 2025 is discussed in section VIII.C.2. of the preamble of this proposed rule. For FY 2025, we are proposing to update the LTCH PPS standard Federal payment rate by 2.8 percent (that is, a 3.2 percent proposed market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act would receive a proposed update of 0.80 percent for FY 2025, which reflects a 2.0 percentage point reduction for failure to submit quality data.

4. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care and links the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and in order to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital VBP Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring HACs, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring readmissions, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-exempt cancer hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs. However, there is no reduction in payment to a PCH that does not report data.

5. Other Proposed Provisions

a. Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we are proposing the creation and testing of a new alternative payment model called the Transforming Episode Accountability Model (TEAM). Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. The underlying issue addressed by the proposed model is that under FFS, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of an episode. Because providers and suppliers are paid for each individual item or service delivered, this may lead to care that is fragmented, unnecessary or duplicative, while making it challenging to invest in quality improvement or care coordination that would maximize patient benefit. We anticipate the proposed model may reduce costs while maintaining or improving quality of care by bundling payment for items and services for a given episode and holding TEAM participants accountable for spending and quality performance, as well as by providing incentives to promote high quality and efficient care.

We propose to create and test an episode-based payment model under the authority at section 1115A of the Act in which selected acute care hospitals would be required to participate. The model would build on and incorporate the most promising model features from other CMS Innovation Center episode-based payment models such as the BPCI Advanced Model and the CJR Model. Testing this new model would allow us to learn more about the patterns of potentially inefficient utilization of health care services, as well as how to improve the beneficiary care experience during care transitions and incentivize quality improvements for common surgical episodes. This information could inform future Medicare payment policy and potentially establish the framework for managing clinical episodes as a standard practice in Traditional Medicare.

Under the proposed model, acute care hospitals in certain selected geographic areas, Core-Based Statistical Areas, would be accountable for five initial episode categories: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment excluding lower extremity joint replacement, and spinal fusion. We believe the model may benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode. The model will also provide an opportunity to evaluate the nature and extent of reductions in the cost of treatment by providing financial incentives for providers to coordinate their efforts to meet patient needs and prevent future costs. The proposed model may benefit beneficiaries by holding hospitals accountable for the quality and cost of care for 30 day episodes after a beneficiary is discharged from the inpatient stay or hospital outpatient procedure, which could encourage investment in infrastructure and redesigned care processes the promote high quality and efficient service delivery that focuses on patient-centered care.

b. Provider Reimbursement Review Board (PRRB)

Section 1878 of the Act (42 U.S.C. 1395oo) established by the Social Security Amendments of 1972, requires the Secretary to appoint individuals to the PRRB for a 3-year term of office. In regulations promulgated after the enactment of this provision, 42 CFR 405.1845 stipulated that no member shall serve more than two consecutive 3-year terms of office. In section X.B. of the preamble of this proposed rule, we discuss our proposal to increase from two to three the number of consecutive terms that a PRRB Member is eligible to serve, while also permitting a Board Member who is designated as Chairperson in their second or third consecutive term to serve a fourth consecutive term as Chairperson. We believe that extending the length of service of Board Members could have an increased effect on the PRRB's productivity and efficiency as well as increase the number of individuals who seek a position on the PRRB.

c. Payment Error Rate Measurement (PERM)

Section 202 of the Further Consolidated Appropriations Act of 2020 (CAA; Pub. L. 116–94) amended Medicaid program integrity requirements in Puerto Rico. Puerto Rico was required to publish a plan, developed by Puerto Rico in coordination with CMS, and approved by the CMS Administrator, not later than 18 months after the CAA's enactment, for how Puerto Rico would develop measures to comply with the PERM requirements of 42 CFR part 431, subpart Q. Puerto Rico published this plan on June 20, 2021, that was approved by the CMS Administrator on June 22, 2021.

In section X.E. of the preamble of this proposed rule, we discuss our proposal to remove the exclusion of Puerto Rico from the PERM program found at 42 CFR 431.954(b)(3). In compliance with section 202 of the CAA, Puerto Rico has developed measures to comply with the PERM requirements of 42 CFR part 431, subpart Q, and we therefore propose that the PERM program become applicable to Puerto Rico. We believe that including Puerto Rico in the PERM program would increase visibility into its Medicaid and CHIP operations and ought to improve its program integrity efforts, that protect taxpayer dollars from improper payments.

d. Hospital CoP Reporting Requirements

Under sections 1861(e)(9) and 1820(e)(3) of the Act, hospitals and CAHs, respectively, under the Medicare and Medicaid programs must meet standards for the health and safety of patients receiving services in those facilities. Rules issued under that statutory authority require such facilities to engage in the surveillance, prevention, and control of health care-associated acute respiratory illnesses. In 2020, we published detailed reporting standards related specifically to COVID–19 for hospitals and CAHs. Those standards sunset on April 30, 2024. In section X.F. of the preamble of this proposed rule, we would establish streamlined standards that apply to a range of acute respiratory illnesses, not just to COVID–19, and would contribute to the ability to combat potential future threats from either existing or potential future sources of such infections.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (CRA) (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of $200 million or more in any 1 year. Based on our estimates, OMB'S Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year. We have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these regulations, and the Departments have provided the following assessment of their impact.

We estimate that the proposed changes for FY 2025 acute care hospital operating and capital payments would redistribute amounts in excess of $200 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $3.0 billion increase in FY 2025 payments, primarily driven by the changes in FY 2025 operating payments, including uncompensated care payments, FY 2025 capital payments, the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program. These changes are relative to payments made in FY 2024. The impact analysis of the capital payments can be found in section I.I. of the Appendix in this proposed rule. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by approximately $40 million in FY 2025 relative to FY 2024.

Our operating payment impact estimate includes the proposed 2.6 percent hospital update to the standardized amount (reflecting the proposed 3.0 percent market basket update reduced by the proposed 0.4 percentage point productivity adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2025, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other

payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related-costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 25 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2023, there were 3,090 IPPS acute care hospitals included in our analysis. This represents approximately 53 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,376 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the update and policy changes to the LTCH PPS for FY 2025 is discussed in section I.J. of this Appendix.

F. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2025 for operating costs of acute care hospitals. The proposed FY 2025 updates to the capital payments to acute care hospitals are discussed in section I.I. of the Appendix in this proposed rule.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2025 operating payments would increase by 2.4 percent, compared to FY 2024. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2023 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2023 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2025 are discussed in section I.I. of this Appendix. We note, as discussed in section III. of the preamble of this proposed rule, we are proposing to adopt the new OMB labor market area delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, effective for the FY 2025 IPPS wage index. We also note, as discussed in section II.A.4. of the Addendum of this proposed rule, we used wage indexes based on the new OMB delineations in determining aggregate payments on each side of the comparison for the changes discussed below, except where otherwise noted (for example, the FY 2024 baseline simulation model). This is consistent with our proposal discussed in section II.A.4. of the Appendix of this proposed rule, to use wage indexes based on the proposed new OMB delineations in the determination of all of the budget neutrality factors in order to properly determine aggregate payments on each side of the comparison for our budget neutrality calculations. We further note that as discussed in that same section, consistent with past practice as finalized in the FY 2005 IPPS final rule (69 FR 49034), we are not adopting the new OMB delineations themselves in a budget neutral manner. We continue to believe that the revision to the labor market areas in and of itself does not constitute an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

We discuss the following changes:

- The effects of the application of the proposed applicable percentage increase of 2.6 percent (that is, a proposed 3.0 percent market basket update with a proposed reduction of 0.4 percentage point for the productivity adjustment), and the proposed applicable percentage increase (including the proposed market basket update and the proposed productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2021, compared to the FY 2020 wage data, to calculate the FY 2025 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that would be effective for FY 2025.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the proposed imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2025. This provision is not budget neutral.
- The effects of the expiration of the special payment status for MDHs beginning January 1, 2025 under current law. As discussed elsewhere in this proposed rule, section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Therefore, under current law, the MDH program will expire for

discharges on or after January 1, 2025. As a result, MDHs that currently receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate plus 75 percent of the difference between payments based on the Federal rate and the hospital-specific rate will be paid based on the Federal rate starting January 1, 2025. As discussed later in this section, because of the timing of this legislation, the payment impacts set forth in Tables I and II of this section and discussed elsewhere in this regulatory impact analysis do not reflect extension of the MDH program for the first quarter of FY 2025. This extension will be reflected in the payment impacts for the final rule.

- The total estimated change in payments based on the proposed FY 2025 policies relative to payments based on FY 2024 policies.

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2025, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible proposed applicable percentage increases that can be applied to the national standardized amount.

We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion on the FY 2025 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED FY 2025 APPLICABLE PERCENTAGE INCREASE FOR THE IPPS				
FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25

PROPOSED FY 2025 APPLICABLE PERCENTAGE INCREASE FOR THE IPPS				
FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.6	0.35	1.85	-0.4

To illustrate the impact of the proposed FY 2025 changes, our analysis begins with a FY 2024 baseline simulation model using: the FY 2024 applicable percentage increase of 2.6 percent; the FY 2024 MS–DRG GROUPER (Version 41); the FY 2024 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2024 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

We note the following at the time this impact analysis was prepared:

- 91 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2025 using a reduced update for these hospitals.
- 87 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2025 using a reduced update for these hospitals.
- 26 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2025 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our comparison illustrates the proposed percent change in payments per case from FY 2024 to FY 2025. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount (see the table earlier in this section that shows the four proposed applicable percentage increases that can be applied to the national standardized amount for FY 2025). We note, section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs for FY 2025 are the same as the four proposed applicable percentage increases in the table earlier in this section.

A second significant factor that affects the changes in hospitals' payments per case from FY 2024 to FY 2025 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2024 that are no longer reclassified in FY 2025. Conversely, payments may increase for hospitals not reclassified in FY 2024 that are reclassified in FY 2025.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2025. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The

top row of the table shows the overall impact on the 3,090 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. There are 2,390 hospitals located in urban areas and 700 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2025 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act) are 1,705, and 1,385, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 1,843 nonteaching hospitals in our analysis, 959 teaching hospitals with fewer than 100 residents, and 288 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs and RRCs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act. Of the hospitals that are not reclassified from urban to rural, there are 142 RRCs, 249 SCHs, and 120 hospitals that are both SCHs and RRCs. Of the hospitals that are reclassified from urban to rural, there are 586 RRCs, 38 SCHs, and 43 hospitals that are both SCHs and RRCs. As previously noted, this analysis does not reflect the recent 3-month extension of the MDH program through December 31, 2024, under section 307 of the CAA, 2024 (Pub. L. 118–42).

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2025 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2025

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of Imputed Floor, the Frontier Wage Index, and Outmigration Adjustment (6)[7]	MDH Expiration (7)[8]	All Proposed FY 2025 Changes (8)[9]
All Hospitals	3,090	2.6	0.0	0.0	0.0	0.0	0.4	-0.2	2.4
By Geographic Location:									
Urban hospitals	2,390	2.6	0.0	0.0	-0.2	0.0	0.4	-0.1	2.4
Rural hospitals	700	2.6	-0.4	0.6	2.4	-0.4	0.1	-1.0	1.9
Bed Size (Urban):									
0-99 beds	643	2.6	-0.2	0.4	-1.2	0.5	0.5	-2.0	0.4
100-199 beds	683	2.6	-0.2	0.0	-0.6	0.6	0.4	-0.4	1.9
200-299 beds	418	2.6	-0.1	-0.1	0.0	0.4	0.4	0.0	2.3
300-499 beds	397	2.6	0.0	0.1	0.3	0.2	0.3	-0.1	2.4
500 or more beds	247	2.5	0.2	-0.2	-0.3	-0.5	0.4	-0.4	3.0
Bed Size (Rural):								0.0	0.0
0-49 beds	350	2.5	-0.5	0.4	1.7	-0.4	0.2	-0.2	0.7
50-99 beds	183	2.6	-0.5	0.3	2.0	-0.4	0.3	-0.1	0.0
100-149 beds	92	2.6	-0.4	0.4	2.4	-0.4	0.1	-0.1	2.2
150-199 beds	44	2.6	-0.2	0.6	2.6	-0.5	0.0	0.0	3.4
200 or more beds	31	2.6	-0.2	1.4	3.1	-0.6	0.2	0.0	4.1
Urban by Region:									
New England	106	2.6	0.0	-1.4	-0.1	-0.4	1.4	-1.9	0.1
Middle Atlantic	280	2.6	-0.1	-1.5	0.6	-0.3	0.9	-0.1	1.6
East North Central	367	2.6	0.1	0.4	-0.9	-0.7	0.1	-0.4	2.9
West North Central	156	2.6	0.0	0.3	-0.7	-0.6	0.5	0.0	3.7
South Atlantic	396	2.6	0.0	1.2	-0.7	-0.5	0.3	-0.2	2.9
East South Central	141	2.6	0.0	2.0	-1.2	-0.6	0.1	-0.1	4.8
West South Central	357	2.6	0.1	1.2	-0.8	-0.6	0.1	-0.1	4.5
Mountain	178	2.6	0.0	1.3	-0.5	0.0	0.3	0.0	1.6
Pacific	358	2.5	0.1	-1.6	1.3	2.6	0.1	0.0	1.2
Rural by Region:									
New England	21	2.6	-0.2	0.3	2.1	-0.6	0.4	-1.9	2.0
Middle Atlantic	53	2.6	-0.3	2.1	5.6	-0.6	0.0	-0.3	3.7
East North Central	111	2.6	-0.3	0.1	2.5	-0.4	0.1	-2.4	0.1
West North Central	79	2.6	-0.5	0.0	0.6	-0.2	0.4	-0.4	1.8
South Atlantic	112	2.6	-0.5	0.1	1.5	-0.4	0.1	-1.2	0.8
East South Central	134	2.5	-0.3	1.5	2.7	-0.6	0.0	-0.6	3.6
West South Central	124	2.5	-0.4	0.6	2.6	-0.5	0.0	-0.4	2.9
Mountain	42	2.4	-0.3	0.7	-0.3	-0.2	0.6	0.0	2.4
Pacific	24	2.6	-0.4	0.0	3.0	-0.3	0.0	0.0	1.5
Puerto Rico									
Puerto Rico Hospitals	51	2.6	-0.5	-2.0	-2.1	-0.5	0.5	0.0	2.5
By Payment Classification:									
Urban hospitals	1,705	2.6	-0.1	0.0	-1.3	0.9	0.6	0.0	2.4
Rural areas	1,385	2.6	0.0	0.0	1.0	-0.7	0.2	-0.3	2.4
Teaching Status:									
Nonteaching	1,843	2.6	-0.2	0.1	-0.1	0.7	0.3	-0.5	1.8

Fewer than 100 residents	959	2.6	-0.1	0.2	0.2	0.0	0.4	-0.2	2.5
100 or more residents	288	2.5	0.2	-0.3	-0.2	-0.5	0.4	0.0	2.8
Urban DSH:									
Non-DSH	325	2.6	-0.1	-0.1	-1.0	-0.3	0.6	-0.2	2.6
100 or more beds	1,009	2.6	0.0	0.0	-1.3	1.1	0.6	0.0	2.5
Less than 100 beds	371	2.6	-0.2	0.1	-1.4	1.0	0.4	-0.5	1.6
Rural DSH:									
Non-DSH	96	2.6	0.0	0.3	0.7	-0.8	0.2	-2.5	-0.6
SCH	248	2.6	-0.4	0.1	0.2	-0.1	0.0	0.0	2.3
RRC	791	2.6	0.1	0.0	1.1	-0.7	0.2	-0.1	2.6
100 or more beds	41	2.6	0.2	0.1	-1.4	-0.8	0.1	-0.6	3.5
Less than 100 beds	209	2.5	-0.4	0.5	3.6	-0.8	0.3	-6.8	-4.1
Urban teaching and DSH:									
Both teaching and DSH	579	2.6	0.0	0.0	-1.3	0.7	0.7	0.0	2.6
Teaching and no DSH	54	2.6	-0.1	-0.3	-0.8	-0.6	0.8	-0.4	2.3
No teaching and DSH	801	2.6	-0.1	0.0	-1.3	1.8	0.3	0.0	2.2
No teaching and no DSH	271	2.6	-0.1	0.1	-1.2	0.0	0.5	0.0	2.8
Special Hospital Types:									
RRC	142	2.6	-0.1	1.3	2.4	-0.3	0.3	-0.9	2.7
RRC with Section 401 Reclassification	586	2.6	0.1	-0.1	1.0	-0.8	0.2	-0.1	2.5
SCH	249	2.5	-0.6	0.1	0.2	-0.1	0.1	0.0	2.1
SCH with Section 401 Reclassification	38	2.6	-0.1	0.0	0.1	0.0	0.0	0.0	2.5
SCH and RRC	120	2.6	-0.4	0.3	1.1	-0.2	0.1	0.0	2.7
SCH and RRC with Section 401 Reclassification	43	2.6	-0.3	0.2	0.2	-0.1	0.0	0.0	2.5
Type of Ownership:									
Voluntary	1,911	2.6	0.0	-0.1	0.1	-0.1	0.4	-0.2	2.3
Proprietary	753	2.6	-0.1	0.8	-0.3	0.7	0.2	-0.1	2.6
Government	425	2.5	0.1	-0.4	-0.2	-0.1	0.1	-0.1	2.7
Medicare Utilization as a Percent of Inpatient Days:									
0-25	1,362	2.6	0.1	0.1	-0.3	0.1	0.3	0.0	2.9
25-50	1,623	2.6	-0.1	-0.1	0.2	-0.1	0.5	-0.3	2.0
50-65	65	2.6	-0.3	-1.5	-0.1	1.6	0.5	-0.3	1.3
Over 65	17	2.2	-2.5	0.6	-0.2	-0.4	2.3	-1.2	-0.5
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	1,955	2.6	-0.1	0.2	0.0	-0.3	0.4	-0.3	2.3
25-50	1,009	2.6	0.1	-0.2	0.0	0.2	0.4	0.0	2.6
50-65	97	2.5	0.0	-1.3	-0.2	2.2	0.1	0.0	1.4
Over 65	29	2.4	0.0	-1.1	-1.4	5.6	0.1	0.0	1.3
FY 2025 Reclassifications:									
All Reclassified Hospitals	1,141	2.6	0.0	0.0	1.1	-0.5	0.2	-0.2	2.4
Non-Reclassified Hospitals	1,949	2.6	-0.1	0.0	-1.5	0.7	0.6	-0.1	2.4
Urban Hospitals Reclassified	965	2.6	0.1	0.0	0.9	-0.5	0.2	-0.2	2.4
Urban Non-reclassified Hospitals	1,438	2.6	-0.1	0.0	-1.8	0.9	0.7	0.0	2.5
Rural Hospitals Reclassified Full Year	294	2.6	-0.4	0.7	2.8	-0.5	0.0	-0.6	2.5
Rural Non-reclassified Hospitals Full Year	393	2.5	-0.4	0.4	1.5	-0.4	0.3	-1.3	1.4
All Section 401 Reclassified Hospitals:	741	2.6	0.1	-0.1	0.8	-0.8	0.2	-0.2	2.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.6	-0.3	0.9	5.2	-0.8	0.4	-3.4	-0.8

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2023, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the payment impact of the proposed hospital rate update, including the proposed 2.6 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.0 percent market basket rate-of-increase reduced by 0.4 percentage point for the proposed productivity adjustment).

[3] This column displays the proposed payment impact of the changes to the Version 42 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2023 MedPAR data, and the permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factors of 0.997301 and 0.999873.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2021 cost report data. This column displays the payment impact of the application of the proposed wage budget neutrality factor. The proposed wage budget neutrality factor is 1.000014.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2025 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2025. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.972192.

[6] This column displays the effects of the proposed rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index 0.981486.

[7] This column shows the combined impact of (1) the imputed floor for all-urban states; (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column displays the impact of the expiration of the MDH status for FY 2025, a non-budget neutral payment provision. As previously noted, this analysis does not reflect the 3-month extension of the MDH program through December 31, 2024 under section 307 of the CAA, 2024 (Pub. L. 118-42).

[9] This column shows the estimated change in proposed payments from FY 2024 to FY 2025.

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a. Effects of the Proposed Hospital Update (Column 1)

As discussed in section V.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.0 percent market basket rate-of-increase reduced by the 0.4 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.6 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.0 percent market basket rate-of-increase reduced by 0.4 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.6 percent update to the hospital-specific rates.

Overall, hospitals would experience a 2.6 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.D. of the preamble of this proposed rule, for FY 2025, we calculated the proposed MS–DRG relative weights using the FY 2023 MedPAR data grouped to the proposed Version 42 (FY 2025) MS–DRGs. The proposed reclassification changes to the GROUPER are described in more detail in section II.C. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the proposed MS–DRGs and proposed relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.997055 and the proposed recalibration cap budget neutrality factor of 0.999617 to the standardized amount.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards (based on OMB standards) that we are proposing to use in FY 2025 are discussed in section III.A.2. of the preamble of this proposed rule. Specifically, we are proposing to implement the new OMB delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, effective beginning with the FY 2025 IPPS wage index.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2025 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2020 and before October 1, 2021. The estimated impact of the proposed updated wage data on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the proposed percentage change in payments when going from a model using the FY 2024 wage index, the labor-related share of 67.6 percent, and having a 100-percent proposed occupational mix adjustment applied, to a model using the proposed FY 2025 pre-reclassification wage index with the proposed labor-related share of 67.6 percent, also having a 100-percent proposed occupational mix adjustment applied, while holding other payment parameters, such as use of the proposed Version 42 MS–DRG GROUPER constant. As noted earlier and as discussed in section II.A.4. of the Addendum of this proposed rule, we used wage indexes based on the new OMB delineations in determining aggregate payments on each side of the comparison/model. The proposed FY 2025 occupational mix adjustment is based on the CY 2022 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2025, we are proposing to calculate the wage budget neutrality factor to ensure that payments under the proposed updated wage data and the proposed labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the proposed wage budget neutrality factor is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2025 wage budget neutrality factor is 0.999957 and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data. Overall, the proposed new wage data and the proposed labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 8.75 percent compared to FY 2024. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the proposed 8.75 percent increase in the national average hourly wage.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2025 relative to FY 2024. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent (as proposed) or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals based on the wage data used for this proposed rule.

Proposed FY 2025 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	76	0
Increase greater than or equal to 5 percent and less than 10 percent	245	105
Increase or decrease less than 5 percent	1,886	582
Decrease greater than or equal to 5 percent and less than 10 percent	151	1
Decrease 10 percent or more	9	0
Unchanged	0	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located, such as hospitals with a § 412.103 reclassification or ''LUGAR'' status). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2025.

By spring of each year, the MGCRB makes reclassification determinations that would be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.976773 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule).

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 2.4 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2025.

e. Effects of the Proposed Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.G.1. of the preamble of this proposed rule, section 4410 of Pub. L. 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2025 rural floor budget neutrality factor to be applied to the wage index of 0.985868, which would reduce wage indexes by 1.4 percent compared to the rural floor provision not being in effect.

Column 5 shows the projected impact of the rural floor with the proposed national rural floor budget neutrality factor applied to the wage index. The column compares the proposed post-reclassification FY 2025 wage index of providers before the proposed rural floor adjustment to the proposed post-reclassification FY 2025 wage index of providers with the proposed rural floor adjustment.

We estimate that 492 hospitals would receive the rural floor in FY 2025. All IPPS hospitals in our model would have their wage indexes reduced by the proposed rural floor budget neutrality adjustment of 0.985868. We project that, in aggregate, rural hospitals would experience a 0.4 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality adjustment because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments, because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to non-rural floor urban hospitals whose wage index is downwardly adjusted by the proposed rural floor budget neutrality factor. Urban hospitals in the Pacific region would experience a 2.6 percent increase in payments primarily due to the application of the rural floor in California.

f. Effects of the Application of the Proposed Imputed Floor, Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of the following: (1) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act, which provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018; (2) section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States;'' and (3) the effects of section 1886(d)(13) of the Act, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index.

These three wage index provisions are not budget neutral and would increase payments overall by 0.4 percent compared to the provisions not being in effect.

Section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index for all-urban States shall not be applied in a budget neutral manner. Therefore, the proposed imputed floor adjustment is estimated to increase IPPS operating payments by approximately $246 million. There are an estimated 99 providers in Connecticut, Washington DC, New Jersey, Puerto Rico, and Rhode Island that would receive the imputed floor wage index.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States, and an estimated 41 hospitals located in Montana, North Dakota, South Dakota, and Wyoming would receive a frontier wage index of 1.0000. We note, the rural floor for Nevada exceeds the frontier state wage index of 1.000, and therefore no hospitals in Nevada receive the frontier state wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $52 million.

In addition, section 1886(d)(13) of the Act provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment would receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are

an estimated 196 providers that would receive the proposed out-migration wage adjustment in FY 2025. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the proposed out-migration increase would be approximately $55 million.

g. Effects of the Expiration of MDH Special Payment Status (Column 7)

Column 7 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180), extended the MDH program (which, under previous law, was to be in effect for discharges before October 1, 2022 only) through December 16, 2022. Section 102 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229) extended the MDH program through December 23, 2022. Section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), extended the MDH program through FY 2024 (that is for discharges occurring before October 1, 2024). As previously noted, section 307 of the CAA, 2024 (Pub. L. 118–42), enacted on March 9, 2024, further extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2025. Hospitals that qualify to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision is not budget neutral, the expiration of this payment provision is estimated to result in a 0.2 percent decrease in payments overall, not taking into consideration the extension through the first quarter of FY 2025. There are currently 173 MDHs, of which we estimate 114 would be paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program were not set to expire. Because those 114 MDHs will no longer receive the blended payment and will be paid only under the Federal rate for FY 2025 discharges beginning on or after January 1, 2025, it is estimated that those hospitals would experience an overall decrease in payments of approximately $151 million. The $151 overall decrease reflects the 3-month extension of the MDH program through December 31, 2024 under section 307 of the CAA, 2024. However, we note that because of the timing of this legislation, the payment impacts set forth in Tables I and II of this section and discussed elsewhere in this regulatory impact analysis do not reflect extension of the MDH program for the first quarter of FY 2025. This extension will be reflected in the payment impacts for the final rule.

h. Effects of All Proposed FY 2025 Changes (Column 8)

Column 8 shows our estimate of the proposed changes in payments per discharge from FY 2024 and FY 2025, resulting from all changes reflected in this proposed rule for FY 2025. It includes combined effects of the year-to-year change of the factors described in previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 2.4 percent for FY 2025 relative to FY 2024 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 8 includes the proposed annual hospital update of 2.6 percent to the national standardized amount. This annual hospital update includes the proposed 3.0 percent market basket rate-of-increase reduced by the 0.4 percentage point proposed productivity adjustment. Hospitals paid under the hospital-specific rate would receive a 2.6 percent proposed hospital update. As described in Column 1, the proposed annual hospital update for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates, combined with the proposed other adjustments described previously and shown in Table I, would result in a 2.4 percent increase in payments in FY 2025 relative to FY 2024.

This column also reflects the estimated effect of outlier payments returning to their targeted levels in FY 2025 as compared to the estimated outlier payments for FY 2024 produced from our payment simulation model. As discussed in section II.A.4.i. of the Addendum to this proposed rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2024. Therefore, our estimate of payments per discharge for FY 2025 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2024 exceed that target by approximately 0.01 percent. Therefore, our estimate of the changes in payments per discharge from FY 2024 to FY 2025 in Column 8 reflects the estimated −0.01 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2025. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which may contribute to our estimate of the changes in payments per discharge from FY 2024 and FY 2025 in Column 8.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.4 percent for FY 2025. Hospitals in urban areas would experience a 2.4 percent increase in payments per discharge in FY 2025 compared to FY 2024. Hospital payments per discharge in rural areas are estimated to increase by 1.9 percent in FY 2025.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2025 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2024 with the estimated average payments per discharge for FY 2025, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 8 of Table I.

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TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2025 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2024 Payment Per Discharge (2)	Estimated Proposed Average FY 2025 Payment Per Discharge (3)	Proposed FY 2025 Changes (4)
All Hospitals	3,090	16,652	16,261	2.4
By Geographic Location:				
Urban hospitals	2,390	17,060	16,654	2.4
Rural hospitals	700	12,247	12,019	1.9
Bed Size (Urban):				
0-99 beds	643	12,134	12,085	0.4
100-199 beds	683	13,366	13,118	1.9
200-299 beds	418	15,193	14,850	2.3
300-499 beds	397	16,898	16,502	2.4
500 or more beds	247	21,433	20,817	3.0
Bed Size (Rural):				
0-49 beds	350	10,128	10,067	0.6
50-99 beds	183	11,663	11,675	-0.1
100-149 beds	92	11,741	11,490	2.2
150-199 beds	44	13,345	12,900	3.4
200 or more beds	31	15,382	14,779	4.1
Urban by Region:				
New England	106	18,210	18,186	0.1
Middle Atlantic	280	20,078	19,763	1.6
East North Central	367	15,998	15,539	2.9
West North Central	156	16,283	15,697	3.7
South Atlantic	396	14,660	14,241	2.9
East South Central	141	14,189	13,544	4.8
West South Central	357	14,932	14,286	4.5
Mountain	178	16,752	16,491	1.6
Pacific	358	21,984	21,713	1.2
Rural by Region:				
New England	21	17,358	17,025	2.0
Middle Atlantic	53	13,891	13,395	3.7
East North Central	111	11,658	11,645	0.1
West North Central	79	12,530	12,314	1.8
South Atlantic	112	11,207	11,121	0.8
East South Central	134	10,751	10,386	3.5
West South Central	124	10,247	9,961	2.9
Mountain	42	14,749	14,429	2.2
Pacific	24	17,216	16,970	1.5
Puerto Rico				
Puerto Rico Hospitals	51	9,604	9,374	2.5
By Payment Classification:				
Urban hospitals	1,705	15,226	14,862	2.4
Rural areas	1,385	17,985	17,569	2.4
Teaching Status:				
Nonteaching	1,843	12,689	12,472	1.7
Fewer than 100 residents	959	15,121	14,751	2.5
100 or more residents	288	24,580	23,919	2.8
Urban DSH:				
Non-DSH	325	13,260	12,926	2.6
100 or more beds	1,009	15,826	15,443	2.5
Less than 100 beds	371	11,106	10,934	1.6
Rural DSH:				
Non-DSH	96	15,806	15,906	-0.6
SCH	248	13,515	13,219	2.2
RRC	791	18,637	18,174	2.5

	Number of Hospitals (1)	Estimated Average FY 2024 Payment Per Discharge (2)	Estimated Proposed Average FY 2025 Payment Per Discharge (3)	Proposed FY 2025 Changes (4)
100 or more beds	41	18,082	17,478	3.5
Less than 100 beds	209	9,186	9,581	-4.1
Urban teaching and DSH:				
Both teaching and DSH	579	17,330	16,897	2.6
Teaching and no DSH	54	14,451	14,122	2.3
No teaching and DSH	801	12,882	12,607	2.2
No teaching and no DSH	271	12,557	12,219	2.8
Special Hospital Types:				
RRC	142	12,581	12,254	2.7
RRC with Section 401 Reclassification	586	19,324	18,852	2.5
SCH	249	12,597	12,350	2.0
SCH with Section 401 Reclassification	38	15,771	15,392	2.5
SCH and RRC	120	14,323	13,957	2.6
SCH and RRC with Section 401 Reclassification	43	17,602	17,168	2.5
Type of Ownership:				
Voluntary	1,911	16,654	16,280	2.3
Proprietary	753	14,635	14,259	2.6
Government	425	19,267	18,757	2.7
Medicare Utilization as a Percent of Inpatient Days:				
0-25	1,362	18,517	18,002	2.9
25-50	1,623	15,303	15,001	2.0
50-65	65	14,505	14,312	1.3
Over 65	17	9,756	9,848	-0.9
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	1,955	14,899	14,565	2.3
25-50	1,009	19,112	18,628	2.6
50-65	97	23,189	22,879	1.4
Over 65	29	22,723	22,434	1.3
FY 2025 Reclassifications:	0	0	0	0.0
All Reclassified Hospitals	1,141	17,808	17,384	2.4
Non-Reclassified Hospitals	1,949	15,325	14,972	2.4
Urban Hospitals Reclassified	965	18,321	17,899	2.4
Urban Non-reclassified Hospitals	1,438	15,405	15,024	2.5
Rural Hospitals Reclassified Full Year	294	12,491	12,191	2.5
Rural Non-reclassified Hospitals Full Year	393	11,900	11,750	1.3
All Section 401 Reclassified Hospitals:	741	18,996	18,551	2.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	11,014	11,100	-0.8

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4. Impact Analysis of Table III: Provider Deciles by Beneficiary Characteristics

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[855] To gain insight into how the IPPS policies could affect health equity, we have added Table III, Provider Deciles by Beneficiary Characteristics, for informational purposes. Table III details providers in terms of the beneficiaries they serve, and shows differences in estimated average payments per case and changes in estimated average payments per case relative to other providers.

As noted in section I.C. of this Appendix, this proposed rule contains a range of proposed policies, and there is a section of the proposed rule where each policy is discussed. Each section includes the rationale for our proposals, including the need for the proposed policy. The information contained in Table III is provided solely to demonstrate the quantitative effects of our proposed policies across a number of health equity dimensions and does not form the basis or rationale for the proposed policies.

Patient populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes, people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality. The CMS Framework for Health Equity was developed with particular attention to disparities in chronic and infectious diseases; as an example of a chronic disease associated with significant disparities, we therefore also detail providers in terms of the percentage of their claims for beneficiaries receiving ESRD Medicare coverage.

Because we do not have data for all characteristics that may identify disadvantaged or underserved patient populations, we use several proxies to capture these characteristics, based on claims data from the FY 2023 MedPAR file and Medicare enrollment data from Medicare's Enrollment Database (EDB), including: race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD–10–CM Z code indicating a ''social determinant of health'' (SDOH), presence of a behavioral health diagnosis code, receiving ESRD Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85. We refer to each of these proxies as characteristics in Table III and the discussion that follows.

a. Race

The first health equity-relevant grouping presented in Table III is race/ethnicity. To assign the race/ethnicity variables used in Table III, we utilized the Medicare Bayesian Improved Surname Geocoding (MBISG) data in conjunction with the MedPAR data. The method used to develop the MBISG data involves estimating a set of six racial and ethnic probabilities (White, Black, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander, and multiracial) from the

[855] Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

surname and address of beneficiaries by using previous self-reported data from a national survey of Medicare beneficiaries, post-stratified to CMS enrollment files. The MBISG method is used by the CMS Office of Minority Health in its reports analyzing Medicare Advantage plan performance on Healthcare Effectiveness Data and Information Set (HEDIS) measures, and is being considered by CMS for use in other CMS programs. To estimate the percentage of discharges for each specified racial/ethnic category for each hospital, the sum of the probabilities for that category for that hospital was divided by the hospital's total number of discharges.

b. Income

The two main proxies for income available in the Medicare claims and enrollment data are dual eligibility for Medicare and Medicaid and Medicare LIS status. Dual-enrollment status is a powerful predictor of poor outcomes on some quality and resource use measures even after accounting for additional social and functional risk factors.[856] Medicare LIS enrollment refers to a beneficiary's enrollment in the low-income subsidy program for the Part D prescription drug benefit. This program covers all or part of the Part D premium for qualifying Medicare beneficiaries and gives them access to reduced copays for Part D drugs. (We note that beginning on January 1, 2024, eligibility for the full low-income subsidy was expanded to include individuals currently eligible for the partial low-income subsidy.) Because Medicaid eligibility rules and benefits vary by state/territory, Medicare LIS enrollment identifies beneficiaries who are likely to have low income but may not be eligible for Medicaid. Not all beneficiaries who qualify for the duals or LIS programs actually enroll. Due to differences in the dual eligibility and LIS qualification criteria and less than complete participation in these programs, sometimes beneficiaries were flagged as dual but not LIS or vice versa. Hence this analysis also used a ''dual or LIS'' flag as a third proxy for low income. The dual and LIS flags were constructed based on enrollment/eligibility status in the EDB during the month of the hospital discharge.

c. Social Determinants of Health (SDOH)

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[857] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. ICD–10–CM contains Z-codes that describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. The presence of ICD–10–CM Z-codes in the range Z55–Z65 identifies beneficiaries with these SDOH characteristics. The SDOH flag used for this analysis was turned on if one of these Z-codes was recorded on the claim for the hospital stay itself (that is, the beneficiary's prior claims were not examined for additional Z-codes). Since these codes are not required for Medicare FFS patients and did not impact payment under the IPPS in FY 2023, we believe they may be underreported in the claims data from the FY 2023 MedPAR file used for this analysis and not reflect the actual rates of SDOH. In 2019, 0.11 percent of all Medicare FFS claims were Z code claims and 1.59 percent of continuously enrolled Medicare FFS beneficiaries had claims with Z codes.[858] However, we expect the reporting of Z codes on claims may increase over time, because of newer quality measures in the Hospital Inpatient Quality Reporting (IQR) Program that capture screening and identification of patient-level, health-related social needs (MUC21–134 and MUC21–136) (87 FR 49201 through 49220). In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), we also finalized a change to the severity designation of the following three ICD–10–CM diagnosis codes from non-CC to CC: Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness) and Z59.02 (Unsheltered homelessness). We also refer the reader to section II.C.12.c.1. of the preamble of this proposed rule, where we discuss our proposal to change the severity level designation of the following seven ICD–10–CM diagnosis codes from non-CC to CC for FY 2025: Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months), and Z59.819 (Housing instability, housed unspecified).

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses, but often experience difficulty accessing care.[859] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[860] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[861] We used the presence of one or more ICD–10–CM codes in the range of F01–F99 to identify beneficiaries with a behavioral health diagnosis.

e. Disability

Beneficiaries with disabilities are categorized as being disabled because of a medically determinable physical or mental impairment(s) that has lasted or is expected to last for a continuous period of at least 12 months or is expected to result in death.[862] Beneficiaries with disabilities often have complex healthcare needs and difficulty accessing care. Beneficiaries with disabilities were classified as such persons for the purposes of this analysis if their original reason for qualifying for Medicare was disability; this information was obtained from Medicare's EDB. We note that this is likely an underestimation of disability because it does not account for beneficiaries who became disabled after becoming entitled to Medicare. This metric also does not capture all individuals who would be considered to have a disability under 29 U.S.C. 705(9)(B).

f. ESRD

Beneficiaries with ESRD have high healthcare needs and high medical spending, and often experience comorbid conditions and poor mental health. Beneficiaries with ESRD also experience significant disparities, such as a limited life expectancy.[863] Beneficiaries were classified as ESRD for the purposes of this analysis if they were receiving Medicare ESRD coverage during the month of the discharge; this information was obtained from Medicare's EDB.

g. Geography

Beneficiaries in some geographic areas—particularly rural areas or areas with concentrated poverty—often have difficulty accessing care.[864] [865] For this impact analysis, beneficiaries were classified on two dimensions: from a rural area and from an area with an area deprivation index (ADI) greater than or equal to 85.

Rural status is defined for purposes of this analysis using the primary Rural-Urban Commuting Area (RUCA) codes 4–10 (including micropolitan, small town, and rural areas) corresponding to each beneficiary's zip code. RUCA codes are defined at the census tract level based on

[856] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[857] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[858] See ''Utilization of Z Codes for Social Determinants of Health among Medicare Fee-for-Service Beneficiaries, 2019,'' available at *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

[859] Viron M, Zioto K, Schweitzer J, Levine G. Behavioral Health Homes: an opportunity to address healthcare inequities in people with serious mental illness. Asian J Psychiatr. 2014 Aug; 10:10–6. doi: 10.1016/j.ajp.2014.03.009.

[860] Cully, J.A., Breland, J.Y., Robertson, S. et al. Behavioral health coaching for rural veterans with diabetes and depression: a patient randomized effectiveness implementation trial. BMC Health Serv Res 14, 191 (2014). *https://doi.org/10.1186/1472-6963-14-191.*

[861] *https://www.cms.gov/cms-behavioral-health-strategy.*

[862] *https://www.ssa.gov/disability/professionals/bluebook/general-info.htm.*

[863] Smart NA, Titus TT. Outcomes of early versus late nephrology referral in chronic kidney disease: a systematic review. Am J Med. 2011 Nov;124(11):1073–80.e2. doi: 10.1016/j.amjmed.2011.04.026. PMID: 22017785.

[864] National Healthcare Quality and Disparities Report chartbook on rural health care. Rockville, MD: Agency for Healthcare Research and Quality; October 2017. AHRQ Pub. No. 17(18)-0001–2–EF available at *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/qdr-ruralhealthchartbook-update.pdf.*

[865] Muluk, S, Sabik, L, Chen, Q, Jacobs, B, Sun, Z, Drake, C. Disparities in geographic access to medical oncologists. *Health Serv Res.* 2022; 57(5): 1035–1044. doi:10.1111/1475–6773.13991.

measures of population density, urbanization, and daily commuting. The ADI is obtained from a publicly available dataset designed to capture socioeconomic disadvantage at the neighborhood level.[866] It utilizes data on income, education, employment, housing quality, and 13 other factors from the American Community Survey and combines them into a single raw score, which is then used to rank neighborhoods (defined at various levels), with higher scores reflecting greater deprivation. The version of the ADI used for this analysis is at the Census Block Group level and the ADI corresponds to the Census Block Group's percentile nationally. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[867] [868] [869] [870] [871] The MedPAR discharge data was linked to the RUCA using beneficiaries' five-digit zip code and to the ADI data using beneficiaries' 9-digit zip codes, both of which were derived from Common Medicare Enrollment (CME) files. Beneficiaries with no recorded zip code were treated as being from an urban area and as having an ADI less than 85.

For each of these characteristics, the hospitals were classified into groups as follows. First, all discharges at IPPS hospitals (excluding Maryland and IHS hospitals) in the FY 2023 MedPAR file were flagged for the presence of the characteristic, with the exception of race/ethnicity, for which probabilities were assigned instead of binary flags, as described further in this section. Second, the percentage of discharges at each hospital for the characteristic was calculated. Finally, the hospitals were divided into four groups based on the percentage of discharges for each characteristic: decile group 1 contains the 10% of hospitals with the lowest rate of discharges for that characteristic; decile group 2 to 5 contains the hospitals with less than or equal to the median rate of discharges for that characteristic, excluding those in decile group 1; decile group 6 to 9 contains the hospitals with greater than the median rate of discharges for that characteristic, excluding those in decile group 10; and decile group 10 contains the 10% of hospitals with the highest rate of discharges for that characteristic. These decile groups provide an overview of the ways in which the average estimated payments per discharge vary between the providers with the lowest and highest percentages of discharges for each characteristic, as well as those above and below the median.

We note that a supplementary provider-level dataset containing the percentage of discharges at each hospital for each of the characteristics in Table III is available on our website.

- Column 1 of Table III specifies the beneficiary characteristic.
- Column 2 specifies the decile group.
- Column 3 specifies the percentiles covered by the decile group.
- Column 4 specifies the percentage range of discharges for each decile group specified in the first column.
- Columns 5 and 6 present the average estimated payments per discharge for FY 2024 and average estimated payments per discharge for FY 2025, respectively.
- Column 7 shows the percentage difference between these averages.

The average payment per discharge, as well as the percentage difference between the average payment per discharge in FY 2024 and FY 2025, can be compared across decile groups. For example, providers with the lowest decile of discharges for Dual (All) or LIS Enrolled beneficiaries have an average FY 2024 payment per discharge of $13,660.95, while providers with the highest decile of discharges for Dual (All) or LIS Enrolled beneficiaries have an average FY 2024 payment per discharge of $21,150.86. This pattern is also seen in the proposed average FY 2025 payment per discharge.

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[866] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[867] 7 U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-inMedicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[868] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[869] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[870] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[871] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

TABLE III. PROVIDER DECILES BY BENEFICIARY CHARACTERISTICS

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Estimated Average Payment Per Discharge - FY 2024 (5)	Estimated Average Proposed Payment Per Discharge - FY 2025 (6)	Percent Change (7)
All Hospitals				16,260.30	16,651.50	2.4%
% Of Discharges for Beneficiaries Who Are American Indian or Alaska Native	1	0 to 10	0.0% - 0.2%	12,845.52	13,124.56	2.2%
	2 to 5	>10 to 50	0.2% - 0.3%	15,348.16	15,727.36	2.5%
	6 to 9	>50 to 90	0.3% - 1.2%	17,921.33	18,333.75	2.3%
	10	>90 to 100	1.2% - 33.6%	15,957.21	16,397.17	2.8%
% Of Discharges for Beneficiaries Who Are Asian or Pacific Islander	1	0 to 10	0.0% - 0.1%	10,473.57	10,702.99	2.2%
	2 to 5	>10 to 50	0.1% - 0.8%	13,290.14	13,671.10	2.9%
	6 to 9	>50 to 90	0.8% - 5.1%	16,772.05	17,187.59	2.5%
	10	>90 to 100	5.1% - 92.0%	22,656.61	22,995.57	1.5%
% Of Discharges for Beneficiaries Who Are Black	1	0 to 10	0.0% - 0.4%	13,832.25	14,080.06	1.8%
	2 to 5	>10 to 50	0.4% - 4.0%	14,821.68	15,123.11	2.0%
	6 to 9	>50 to 90	4.0% - 23.5%	17,080.67	17,516.57	2.6%
	10	>90 to 100	23.5% - 93.8%	18,997.23	19,595.85	3.2%
% Of Discharges for Beneficiaries Who Are Hispanic	1	0 to 10	0.3% - 1.0%	12,435.74	12,772.55	2.7%
	2 to 5	>10 to 50	1.0% - 2.6%	14,257.78	14,691.24	3.0%
	6 to 9	>50 to 90	2.6% - 21.4%	17,778.62	18,146.78	2.1%
	10	>90 to 100	21.4% - 98.3%	19,330.76	19,669.91	1.8%
% Of Discharges for Beneficiaries Who Are Multiracial	1	0 to 10	0.0% - 1.5%	13,895.43	14,155.14	1.9%
	2 to 5	>10 to 50	1.5% - 2.1%	15,686.87	16,011.58	2.1%
	6 to 9	>50 to 90	2.1% - 3.0%	16,999.10	17,451.67	2.7%
	10	>90 to 100	3.0% - 11.3%	17,951.68	18,547.58	3.3%
% Of Discharges for Beneficiaries Who Are White	1	0 to 10	0.1% - 47.2%	21,475.24	21,878.53	1.9%
	2 to 5	>10 to 50	47.2% - 85.1%	17,799.94	18,243.67	2.5%
	6 to 9	>50 to 90	85.1% - 95.1%	14,121.23	14,461.29	2.4%
	10	>90 to 100	95.1% - 98.5%	12,323.83	12,591.33	2.2%
% Of Discharges for Beneficiaries Who Are Dual (All) Enrolled During the Month of Discharge	1	0 to 10	0.0% - 10.7%	13,568.10	13,938.58	2.7%
	2 to 5	>10 to 50	10.7% - 24.7%	14,829.70	15,246.63	2.8%
	6 to 9	>50 to 90	24.7% - 50.4%	17,950.88	18,336.68	2.1%
	10	>90 to 100	50.4% - 100.0%	21,301.78	21,514.12	1.0%
% Of Discharges for Beneficiaries Who Are LIS Enrolled During the Month of Discharge	1	0 to 10	0.0% - 12.1%	13,630.00	14,001.92	2.7%
	2 to 5	>10 to 50	12.1% - 26.8%	14,978.23	15,391.56	2.8%
	6 to 9	>50 to 90	26.8% - 52.5%	17,815.48	18,202.77	2.2%
	10	>90 to 100	52.5% - 100.0%	21,182.55	21,408.88	1.1%
	1	0 to 10	0.0% - 12.1%	13,660.95	14,036.15	2.7%

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Estimated Average Payment Per Discharge - FY 2024 (5)	Estimated Average Proposed Payment Per Discharge - FY 2025 (6)	Percent Change (7)
% Of Discharges for Beneficiaries Who Are Dual (All) or LIS Enrolled During the Month of Discharge	2 to 5	>10 to 50	12.1% - 27.0%	14,965.00	15,377.71	2.8%
	6 to 9	>50 to 90	27.0% - 52.6%	17,836.77	18,224.34	2.2%
	10	>90 to 100	52.6% - 100.0%	21,150.86	21,377.86	1.1%
% Of Discharges for Beneficiaries with a Z code reported related to SDOH **	1	0 to 10	0%	12,492.20	12,847.48	2.8%
	2 to 5	>10 to 50	0.0% - 1.6%	15,092.40	15,446.61	2.3%
	6 to 9	>50 to 90	1.6% - 6.2%	17,095.45	17,514.79	2.5%
	10	>90 to 100	6.2% - 100.0%	17,897.68	18,320.27	2.4%
% Of Discharges for Beneficiaries with a Behavioral Health Diagnosis	1	0 to 10	0.0% - 35.7%	18,557.63	18,945.84	2.1%
	2 to 5	>10 to 50	35.7% - 46.8%	16,964.61	17,366.09	2.4%
	6 to 9	>50 to 90	46.8% - 57.8%	15,357.79	15,754.77	2.6%
	10	>90 to 100	57.8% - 100.0%	14,516.23	14,732.27	1.5%
% Of Discharges for Beneficiaries who come from rural areas	1	0 to 10	0.0% - 0.8%	17,290.61	17,489.71	1.2%
	2 to 5	>10 to 50	0.8% - 14.1%	16,746.17	17,126.20	2.3%
	6 to 9	>50 to 90	14.1% - 93.4%	15,742.98	16,228.51	3.1%
	10	>90 to 100	93.4% - 100.0%	12,102.56	12,315.08	1.8%
% Of Discharges for Beneficiaries with ESRD coverage **	1	0 to 10	0%	11,483.71	11,768.20	2.5%
	2 to 5	>10 to 50	0.0% - 3.9%	13,532.58	13,772.35	1.8%
	6 to 9	>50 to 90	3.9% - 9.1%	16,801.79	17,238.04	2.6%
	10	>90 to 100	9.1% - 28.0%	21,446.01	22,017.76	2.7%
% Of Discharges for Beneficiaries with Disability	1	0 to 10	0.0% - 16.0%	14,288.84	14,594.67	2.1%
	2 to 5	>10 to 50	16.0% - 25.8%	15,808.80	16,188.32	2.4%
	6 to 9	>50 to 90	25.8% - 38.1%	17,173.92	17,595.37	2.5%
	10	>90 to 100	38.1% - 100.0%	18,104.93	18,564.04	2.5%
% Of Discharges for Beneficiaries who live in an area with ADI >= 85	1	0 to 10	0.0% - 0.3%	18,862.14	19,029.73	0.9%
	2 to 5	>10 to 50	0.3% - 10.3%	16,913.75	17,263.24	2.1%
	6 to 9	>50 to 90	10.3% - 46.6%	15,059.70	15,571.55	3.4%
	10	>90 to 100	46.6% - 100.0%	11,413.20	11,753.43	3.0%

* Decile group 1 contains the 10% of hospitals with the lowest rate of discharges for that characteristic; decile group 2 to 5 contains the hospitals with less than or equal to the median rate of discharges for that characteristic, excluding those in decile group 1; decile group 6 to 9 contains the hospitals with greater than the median rate of discharges for that characteristic, excluding those in group 10; and decile group 10 contains the 10% of hospitals with the highest rate of discharges for that characteristic.

** Greater than 10 percent of providers did not report discharges associated with this characteristic. Therefore, we have randomly allocated those providers to decile groups 1 and 2.

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G. Effects of Other Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.D. of this Appendix A, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of the Proposed Policy Changes Relating to New Medical Service and Technology Add-On Payments

a. Proposed FY 2025 Status of Technologies Approved for FY 2024 New Technology Add-On Payments

In section II.E.4. of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for the 24 technologies listed in the following table in FY 2025 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this proposed rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2025 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table are estimates for the 24 new technology add-on payments which we are proposing to continue in FY 2025:

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FY 2025 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS PROPOSED TO CONTINUE FOR FY 2025

Technology Name	Estimated Cases	Proposed FY 2025 NTAP Amount (65 % or 75 %)	Estimated Total FY 2025 Impact
Thoraflex™ Hybrid Device	800	$22,750.00	$18,200,000.00
ViviStim® Paired VNS System	135	$23,400.00	$3,159,000.00
GORE® TAG® Thoracic Branch Endoprosthesis	386	$27,807.00	$10,733,502.00
Cerament® G	1,610	$4,918.55	$7,918,865.50
iFuse Bedrock Granite Implant System	1,480	$9,828.00	$14,545,440.00
CYTALUX® (pafolacianine) (ovarian indication)	50	$2,762.50	$138,125.00
CYTALUX® (pafolacianine) (lung indication)	300	$2,762.50	$828,750.00
EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)	157	$6,504.07	$1,021,138.99
Lunsumio™ (mosunetuzumab)	40	$17,492.10	$699,684.00
REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk)	2,628	$6,789.25	$17,842,149.00
SPEVIGO® (spesolimab)	76	$33,236.45	$2,525,970.20
TECVAYLI™ (teclistamab-cqyv)	1906	$8,940.54	$17,040,669.24
TERLIVAZ® (terlipressin)	1146	$16,672.50	$19,106,685.00
Aveir™ AR Leadless Pacemaker	245	$10,725.00	$2,627,625.00
Aveir™ Dual-Chamber Leadless Pacemaker	2,250	$15,600.00	$35,100,000.00
Ceribell Status Epilepticus Monitor	2,477	$913.90	$2,263,730.30
DETOUR System	600	$16,250.00	$9,750,000.00
DefenCath™ (taurolidine/heparin)	12,000	$17,111.25	$205,335,000.00
EchoGo Heart Failure 1.0	19,656	$1,023.75	$20,122,830.00
Phagenyx® System	294	$3,250.00	$955,500.00
REZZAYO™ (rezafungin for injection)	795	$4,387.50	$3,488,062.50
SAINT Neuromodulation System	25	$12,675.00	$316,875.00
TOPS™ System	1,200	$11,375.00	$13,650,000.00
XACDURO® (sulbactam/durlobactam)	654	$13,680.00	$8,946,720.00
Aggregate Estimated Total FY 2025 Impact			**$416,316,321.73**

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b. Proposed FY 2025 Applications for New Technology Add-On Payments

In sections II.E.5. and 6. of the preamble to this proposed rule are 27 discussions of technologies with respect to add-on payments for new medical services and technologies for FY 2024 (including Casgevy™ (exagamglogene autotemcel) for which the applicant submitted a single application for two separate indications, each of which is discussed separately). We note that of the 39 applications (23 alternative and 16 traditional) we received, 8 applications were not eligible for consideration for new technology add-on payment (7 alternative and 1 traditional), and 5 applicants withdrew their application (2 alternative and 3 traditional) prior to the issuance of this proposed rule (including the withdrawal of the application for DefenCath™ (taurolidine/heparin), which received conditional approval for new technology add-on payments for FY 2024, subsequently was eligible to receive new technology add-on payments beginning with discharges on or after January 1, 2024, and for which we are proposing to continue making new technology add-on payments for FY 2025). As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under

section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.E.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are designated under the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2- to 3-year newness period, as discussed in section II.E.1.a.(1). of the preamble this proposed rule, and must also still meet the cost criterion.

As also discussed in section II.E.6. of the preamble of this proposed rule, we are proposing to approve 15 new technology add-on payments for 14 alternative pathway applications submitted for FY 2025 new technology add-on payments (including ZEVTERA™ (ceftobiprole medocaril) for which the applicant submitted a single application for multiple indications, and for which we are proposing two separate new technology add-on payments).

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the 14 technologies that applied under the alternative pathway, if approved, would be approximately $172.7 million for FY 2025. Total estimated FY 2025 payments for new technologies that are designated as a QIDP are approximately $5.6 million, and the total estimated FY 2025 payments for new technologies that are part of the Breakthrough Device program are approximately $167 million. Because cost or volume information has not yet been provided for 3 of the 14 technologies under the alternative pathway, we have not included those technologies in the estimate. We did not receive any LPAD applications for add-on payments for new technologies for FY 2025. We note that the estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the technologies discussed in section II.E.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2025 under the traditional pathway. Consequently, it is premature to estimate the potential payment impact of these technologies for any potential new technology add-on payments for FY 2025. We note that, as in past years, if any of the technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2025, we would discuss the estimated payment impact for FY 2025 in the FY 2025 IPPS/LTCH PPS final rule.

2. Medicare DSH Uncompensated Care Payments and Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section IV.E. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has reported uncompensated care. Each hospital that is eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments (UCP) to DSH-eligible hospitals for FY 2025, which is $6,498,135,150.00. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 62.14 percent. For FY 2024, the amount available to be distributed for uncompensated care was $5,938,006,756.87 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 59.29 percent. In addition, eligible IHS/Tribal hospitals and hospitals located in Puerto Rico are estimated to receive approximately $91,084,288 million in supplemental payments in FY 2025, as determined based on the difference between each hospital's FY 2022 UCP (increased by 9.43 percent, which is the projected change between the FY 2025 total uncompensated care payment amount and the total uncompensated care payment amount for FY 2022) and its FY 2025 UCP as calculated using the methodology for FY 2025. If this difference is less than or equal to zero, the hospital will not receive a supplemental payment. For this proposed rule, the total proposed UCP and proposed supplemental payments equal approximately $6.589 billion. For FY 2025, we are proposing to use 3 years of data on uncompensated care costs from Worksheet S–10 of the FYs 2019, 2020, and 2021 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the methodology for calculating Factor 3 for FY 2025, we refer readers to section IV.E. of the preamble of this proposed rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section IV.D. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare UCP along with changes to supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico, we compared total UCP and supplemental payments estimated in the FY 2024 IPPS/LTCH PPS final rule correction notice (88 FR 68484) to the combined total of the proposed UCP and the proposed supplemental payments estimated in this FY 2025 IPPS/LTCH PPS proposed rule. For FY 2024, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 59.29 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2024 IPPS/LTCH PPS final rule. For FY 2025, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2025 absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 62.14 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this proposed rule, the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals are calculated as the difference between the hospital's adjusted base year amount (as determined based on the hospital's FY 2022 uncompensated care payment) and the hospital's FY 2025 uncompensated care payment.

Our analysis included 2,422 hospitals that are projected to be DSH-eligible in FY 2025. Our analysis did not include hospitals that had terminated their participation in the Medicare program as of February 2, 2024, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 23 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on UCP and supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be DSH-eligible in FY 2025, by hospital characteristic, is presented in the following table:

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MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2025 DSHS BY HOSPITAL TYPE					
	Number of Estimated DSHs (1)	FY 2024 Final Rule Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2025 Proposed Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2024 - FY 2025 ($ in millions) (4)	Percent Change*** (5)
Total	**2,422**	**$6,021**	**$6,589**	**$568**	**9.43%**
By Geographic Location					
Urban Hospitals	1,941	5,687	6,210	523	9.20
Other Urban Areas	1,013	2,573	2,771	198	7.70
Large Urban Areas	928	3,114	3,439	325	10.44
Rural Hospitals	481	335	380	45	13.47
Bed Size (Urban)					
0 to 99 Beds	382	230	267	37	16.33
100 to 249 Beds	798	1,289	1,408	119	9.23
250+ Beds	761	4,168	4,535	367	8.79
Bed Size (Rural)					
0 to 99 Beds	367	183	205	23	12.33
100 to 249 Beds	105	121	141	20	16.89
250+ Beds	9	31	33	2	6.86
Urban by Region					
New England	85	153	164	11	6.89
Middle Atlantic	223	653	707	54	8.34
South Atlantic	313	640	656	16	2.44
East North Central	107	305	331	26	8.48
East South Central	331	1,477	1,602	125	8.45
West North Central	129	365	394	29	7.81
West South Central	245	1,238	1,409	171	13.83
Mountain	145	255	281	26	10.14
Pacific	318	525	584	59	11.25
Puerto Rico	45	75	82	7	9.33
Rural by Region					
New England	9	10	10	0	3.27
Middle Atlantic	36	19	22	3	17.40
South Atlantic	69	41	45	4	8.99
East North Central	31	20	24	4	21.25
East South Central	84	94	108	14	14.43
West North Central	115	66	74	7	11.12
West South Central	106	70	78	8	12.14
Mountain	23	9	12	3	27.31
Pacific	8	5	7	2	29.16
By Payment Classification					
Urban Hospitals	1,350	3,178	3,481	304	9.56
Large Urban Areas	703	1,882	2,090	207	11.00
Other Urban Areas	647	1,295	1,392	97	7.47
Rural Hospitals	1,072	2,844	3,108	264	9.29
Teaching Status					

MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2025 DSHS BY HOSPITAL TYPE					
	Number of Estimated DSHs (1)	FY 2024 Final Rule Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2025 Proposed Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2024 - FY 2025 ($ in millions) (4)	Percent Change*** (5)
Nonteaching	1,321	1,533	1,700	167	10.88
Fewer than 100 residents	822	2,134	2,309	175	8.20
100 or more residents	279	2,354	2,580	226	9.61
Type of Ownership					
Voluntary	1,531	3,482	3,790	308	8.85
Proprietary	526	856	938	82	9.52
Government	365	1,683	1,861	178	10.60
Medicare Utilization Percent****					
0 to 25	1,225	4,274	4,695	420	9.84
25 to 50	1,165	1,735	1,882	147	8.47
50 to 65	24	11	11	0	2.91
Greater than 65	8	1	2	0	27.26
Medicaid Utilization Percent****					
0 to 25	1,357	2,378	2,596	218	9.17
25 to 50	931	2,861	3,107	246	8.61
50 to 65	105	512	581	70	13.58
Greater than 65	29	271	305	34	12.66

Source: Dobson | DaVanzo analysis of 2019, 2020, and 2021 Hospital Cost Reports.
*Dollar UCP calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, UCP and supplemental payments are estimated to be $6,021 million in FY 2024, and UCP and supplemental payments are estimated to be $ 6,589 million in FY 2025.
** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.
*** Percentage change is determined as the difference between Medicare UCP and supplemental payments modeled for this FY 2025 IPPS/LTCH PPS proposed rule (column 3) and Medicare UCP and supplemental payments modeled for the FY 2024 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare UCP and supplemental payments modeled for the FY 2024 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.
****Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

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The changes in projected FY 2025 UCP and supplemental payments compared to the total of UCP and supplemental payments in FY 2024 are driven by increases in Factor 1 and Factor 2. The proposed Factor 1 has increased from the FY 2024 final rule's Factor 1 of $10.015 billion to this proposed rule's Factor 1 of $10.457 billion. The proposed Factor 2 has increased from FY 2024 final rule's Factor 2 of 59.29 percent to this proposed rule's Factor 2 of 62.14 percent. In addition, we note that there is a slight increase in the number of projected DSH-eligible hospitals to 2,422 at the time of the development for this proposed rule compared to the 2,384 DSHs in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58640). Based on the changes, the impact analysis found that, across all projected DSH-eligible hospitals, FY 2025 UCP and supplemental payments are estimated at approximately $6.589 billion, or an increase of approximately 9.43 percent from FY 2024 UCP and supplemental payments (approximately $6.021 billion). While the changes result in a net increase in the total amount available to be distributed in UCP and supplemental payments, the projected payment increases vary by hospital type. This redistribution of payments is caused by changes in Factor 3 and the amount of the supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than 9.43 percent indicates that hospitals within the specified category are projected to experience a smaller increase in payments, on average, compared to the universe of projected FY 2025 DSH-eligible hospitals. Conversely, a percentage change greater than 9.43 percent indicates that a hospital type is projected to have a larger increase compared to the overall average. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the supplemental payment.

Rural hospitals, in general, are projected to experience a slightly larger increase in UCP compared to the increase their urban counterparts are projected to experience. Overall, rural hospitals are projected to receive a 13.47 percent increase in payments, while urban hospitals are projected to receive a 9.20 percent increase in payments, which is slightly less than the overall hospital average.

By bed size, rural hospitals with 0 to 99 beds and rural hospitals with 100 to 249 beds are projected to receive larger than average increases of a 12.33 percent and 16.89 percent, respectively, while rural hospitals with 250+ beds are projected to receive a smaller than average increase of 6.86 percent. Among urban hospitals, the smallest urban hospitals, those with 0 to 99 beds, are projected to receive an increase in payments that is greater than the overall hospital average, an increase of 16.33 percent. In contrast, larger urban hospitals with 100–249

beds and urban hospitals with 250+ beds are projected to receive 9.23 and 8.79 percent increases in payments, respectively.

By region, rural hospitals are projected to receive a varied range of payment changes. Rural hospitals in the New England and South Atlantic regions are projected to receive smaller than average increases in payments. Rural hospitals in all other regions are projected to receive larger than average increases in payments. Urban hospitals in the West South Central, Mountain, and Pacific regions are projected to receive larger than average increases in payments, while urban hospitals in all other regions are projected to receive smaller than average increases in payments.

By payment classification, although hospitals in urban payment areas overall are expected to receive a 9.56 percent increase in UCP and supplemental payments, hospitals in large urban payment areas are projected to receive a larger than average increase in payments of 11.00 percent. In contrast, hospitals in other urban payment areas and hospitals in rural payment areas are projected to receive a smaller than average increase in payments of 7.47 and 9.29 percent, respectively.

Nonteaching hospitals and teaching hospitals with 100+ residents are projected to receive a larger than average payment increase of 10.88 percent and 9.60 percent, respectively. Teaching hospitals with fewer than 100 residents are projected to receive smaller than average payment increases of 8.20 percent. Voluntary hospitals are projected to receive smaller than average increases of 8.85 percent, while government-owned hospitals and proprietary hospitals are expected to receive a larger than average payment increase of 10.60 percent and 9.52 percent, respectively. Hospitals with less than 25 percent Medicare utilization and those with greater than 65 percent Medicare utilization are projected to receive larger than average increases of 9.84 percent and 27.26 percent, respectively, while hospitals with Medicare utilization between 25–50 percent and 50–65 percent are projected to receive smaller than average payment increases of 8.47 percent and 2.91 percent, respectively. Hospitals with 50–65 percent Medicaid utilization and those with greater than 65 percent Medicaid utilization are projected to receive larger than average increases in payments of 13.58 and 12.66 percent, respectively, while hospitals with less than 25 percent Medicaid utilization and those with Medicaid utilization between 25–50 percent are projected to receive smaller than average increases of 9.17 percent and 8.61 percent, respectively.

The impact table reflects the modeled FY 2025 UCP and supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $91.1 million in FY 2025.

3. Effects of the Changes to Low-Volume Hospital Payment Adjustment Policy

In section V.D. of the preamble of this proposed rule, we discuss the extension of the temporary changes to the low-volume hospital payment policy originally provided for by the Affordable Care Act and extended by subsequent legislation. Specifically, section 306 of the CAA, 2024 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through December 31, 2024. Beginning January 1, 2025, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005, will resume. Effective for FY 2025, discharges occurring on or after January 1, 2025 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. We recognize the importance of this extension with respect to the goal of advancing health equity by addressing the health disparities that underlie the health system, which is one of CMS' strategic pillars and a Biden-Harris Administration priority, as described in section I.A.2. of the preamble of this proposed rule. The provisions of section 306 of the CAA, 2024 are projected to increase payments to IPPS hospitals by approximately $87 million in FY 2025 relative to what the payments would have been in the absence of section 306.

Based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment policy for FY 2025 discharges occurring on or after January 1, 2025 would decrease aggregate low-volume hospital payments by $261 million in FY 2025 as compared to FY 2024. These payment estimates were determined based on the estimated payments for the 608 providers that are expected to no longer qualify under the criteria that will apply beginning on January 1, 2025. These impacts were calculated using the same methodology used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of this Appendix A of this proposed rule.

4. Effects of the Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)

In section V.F.2. of this proposed rule we are proposing to implement section 4122 of the CAA, 2023, which requires that the Secretary initiate an application round to distribute 200 residency positions (also referred to as slots) with at least 100 of the positions being distributed for psychiatry or psychiatry subspecialty residency programs. The residency positions distributed under section 4122 are effective July 1, 2026.

We are proposing to first distribute slots by prorating the available 200 positions among all qualifying hospitals such that each qualifying hospital receives up to 1.00 FTE—that is, 1.00 FTE or a fraction of 1.00 FTE. We are proposing that a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories, as defined at section 1886(h)(10)(F)(iii) of the Act.[872] We are proposing that if any residency slots remain after distributing up to 1.00 FTE to each qualifying hospital, we will prioritize the distribution of the remaining slots based on the HPSA score associated with the program for which each qualifying hospital is applying using the methodology we finalized for purposes of implementing section 126 of the CAA, 2021 (86 FR 73434 through 73440). Using this HPSA prioritization method, we are proposing to limit a qualifying hospital's total award under section 4122 of the CAA, 2023, to 10.00 additional FTEs consistent with section 1886(h)(10)(C)(i) of the Act. We believe including such a prioritization will further support the training of residents in underserved and rural areas thereby helping to address physician shortages and the larger issue of health inequities in these areas.

The Office of the Actuary estimates an increase of $10 million in Medicare payments to teaching hospitals for FY 2026, and an increase in Medicare payments to teaching hospitals of $280 million for FYs 2026 through 2030 (over 5 years). In total, for FYs 2026 through 2036, Medicare payments to teaching hospitals are estimated to increase by $740 million.

In addition, we are proposing a modification to our methodology for distributing slots under section 126 of the CAA, 2021. Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to the same four categories of hospitals. Section 126 of the CAA, 2021, makes available 1,000 residency positions and therefore, at least 100 residency positions must be distributed to hospitals qualifying in each of the four categories. In the final rule implementing section 126 of the CAA, 2021, we stated we would track progress in meeting all statutory

[872] Category One consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or have been reclassified being located in a rural area (pursuant to section 1886(d)(8)(E) of the Act). Category Two consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(10)(F)(iv) of the Act) is greater than the otherwise applicable resident limit. Category Three consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME) or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). Category Four consists of hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary.

requirements and evaluate the need to modify the distribution methodology in future rulemaking (86 FR 73441). To date, we have the completed the distribution of residency slots under rounds 1 and 2 of the section 126 distributions and have determined that only 12.76 DGME slots and 18.06 IME slots were distributed to hospitals qualifying under Category Four. We are proposing that in rounds 4 and 5 we will prioritize the distribution of slots to hospitals that qualify under Category Four, regardless of HPSA score, to ensure that at least 100 residency slots are distributed to these hospitals. The remaining slots awarded under rounds 4 and 5 will be distributed using the existing methodology based on HPSA score (86 FR 73434 through 73440). That is, the remaining slots will be distributed to hospitals qualifying under Category One, Category Two, or Category Three, or hospitals that meet the definition of more than one of these categories, based on the HPSA score associated with the program for which each hospital is applying. We believe there is a minimal impact associated with this proposed change in methodology as the number of total slots distributed will remain the same.

5. Effects of Proposed Changes to Additional Payment for Hospitals With a High Percentage of ESRD Beneficiary Discharges

As discussed in section V.I. of the preamble of this proposed rule, we are proposing to update our payment methodology for determining the ESRD add-on payment for hospitals with a high percentage of ESRD beneficiary discharges. Under § 412.104(b), the ESRD add-on is based on the average length of stay (in days) for ESRD beneficiaries in the hospital, expressed as a ratio to 1 week (7 days), multiplied by the estimated weekly cost of dialysis, then multiplied by the number of ESRD beneficiary discharges (Worksheet E Part A Column 1 line 41.01). We are proposing that effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis would be calculated as the ESRD PPS base rate (as defined in 42 CFR 413.171) multiplied by three. As discussed in section V.I. of the preamble of this proposed rule, under our proposal, the CY 2025 ESRD PPS base rate would be used for all cost reports beginning during Federal FY 2025 (that is, for cost reporting periods starting on or after October 1, 2024, through September 30, 2025).

Our impact analysis includes 91 hospitals that were eligible for the ESRD add-on payment based on the historical composite rate in the FY 2017 cost report data, which is a historical year that has a high percentage of final settled cost report data regarding ESRD add-on payments. To estimate the impact of the proposed change to the payment methodology, we compared total ESRD add-on payments from the December 2023 update of the FY 2017 cost report data to the estimated FY 2025 ESRD add-on payments using, for illustrative purposes, the CY 2024 ESRD PPS base rate published in the CY 2024 ESRD PPS final rule (88 FR 76345), which is $271.02. (As previously noted, under our proposal, the CY 2025 ESRD PPS base rate would be used for all cost reports beginning during Federal FY 2025 (that is, for cost reporting periods starting on or after October 1, 2024, through September 30, 2025).) The total ESRD add-on payments based on the FY 2017 cost report data are approximately $22 million. The total estimated FY 2025 ESRD add-on payments under this proposal, as estimated using the CY 2024 ESRD PPS base rate, would be approximately $31.4 million. Therefore, we estimate the proposal would increase ESRD add-on payments by approximately $10 million.

6. Estimated Effects of the Proposed IPPS Payment Adjustment for Establishing and Maintaining Access to Essential Medicines

As discussed in section V.K.1. of the preamble of this proposed rule, we propose IPPS payment adjustments for the additional resource costs that small, independent hospitals incur in establishing and maintaining access to a 6-month buffer stock of one or more essential medicine(s). We propose that the payment adjustments would commence for cost reporting periods beginning on or after October 1, 2024.

We propose to make this payment adjustment under the IPPS for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines under section 1886(d)(5)(I) of the Act. We are not proposing to make the IPPS payment adjustment budget neutral under the IPPS.

The data currently available to calculate a spending estimate for FY 2025 under the IPPS is limited. However, we believe the methodology described in this section to calculate this spending estimate under the IPPS for FY 2025 is reasonable based on the information available.

To estimate total spending associated with this proposed policy under the IPPS, we used the following information for all eligible hospitals with completed 12-month or greater cost reporting periods concluding in CY 2021 (the most recent cost reporting period for which data was available):

- Estimated spend per eligible hospital on its applicable essential medicines, expressed as a percentage of the total Drugs Charged to Patients cost center, as found on Worksheet B, Part 1, line 73, column 26 on Form CMS–2552–2010. For purposes of this estimate, we believe it is reasonable to assume that the cost of a given hospital's essential medicines will be 1 percent of its total Drugs Charged to Patients costs.
- Multiplicative factor of 50 percent to estimate the total cost of the essential medicines that are in the 6-month buffer stock.
- Assumed cost of carrying essential medicines, expressed as a percentage of the total cost of the essential medicines that are in the buffer stock. Based on commenter feedback on the CY 2024 OPPS/ASC proposed rule,[873] we believe it is reasonable to assume for purposes of this spending estimate a cost of carrying essential medicines of 20 percent of the cost of the essential medicines themselves. This assumption of a 20 percent cost of carrying would apply to any size of buffer stock of essential medicine.
- The provider-specific inpatient Medicare share percentage, expressed as the percentage of inpatient Medicare costs to total hospital costs.

To calculate the estimated aggregate IPPS payments under this proposed policy, we multiplied together the four factors listed for each eligible hospital and summed across all eligible hospitals. Based on the latest hospital cost report data available, we identified 493 IPPS hospitals that would potentially be eligible for this proposed payment. These 493 IPPS hospitals are those providers that: (1) had 100 or fewer beds as defined in § 412.105(b); and (2) answered ''N'' to line 140, column 1 and did not fill out any part of lines 141 through 143 on Worksheet S2 Part I on Form CMS–2552–10. We estimate that the aggregate FY 2025 IPPS payments under this proposed policy, given the assumptions detailed previously, would be approximately $0.3 million, and the average IPPS payment per eligible hospital would be approximately $620. As noted previously and as stated in section V.K.2 of the preamble of this proposed rule, we are not proposing to make this policy budget neutral under the IPPS.

We also estimated the total costs for eligible hospitals to establish and maintain buffer stocks of essential medicines in order to inform the public what portion of the total costs would be separately paid under the proposed policy. To calculate this, we multiplied together the first three factors listed previously for each eligible hospital, but not the fourth factor (*i.e.* we did not multiply by the provider specific inpatient Medicare share percentage) and summed across all eligible hospitals. We estimate that the total costs for eligible hospitals to establish and maintain buffer stocks of essential medicines would be approximately $2.8 million, and the average cost per eligible hospital would be approximately $5,610. The IPPS payments under this proposed policy represent approximately 11 percent of that amount, or $0.3 million.

As discussed earlier, our estimate was calculated at the hospital level and then summed. However, for illustrative purposes the calculation can be described alternatively as starting with the aggregated total Drugs Charged to Patients across all 493 eligible hospitals of approximately $2.8 billion, assuming the annual cost of essential medicines to be 1 percent of that amount or $28 million (= $2.8 billion * .01), calculating the cost of 6 months of essential medicines as half that amount or $14 million (= $28 million * .50), assuming that the cost of carrying essential medicines is 20 percent of that amount or $2.8 million (= $14 million * .20), and then calculating the Medicare inpatient share of that amount at 11 percent or $0.3 million (= $2.8 million * .11).

We seek comment on these assumptions and estimates.

7. Effects Under the Hospital Readmissions Reduction Program for FY 2025

In section V.K. of the preamble of this proposed rule, we note that we are not proposing to add, modify, or remove any

[873] *https://www.regulations.gov/comment/CMS-2023-0120-3326.*

policies for the FY 2025 Hospital Readmissions Reduction Program; the policies finalized in FY 2023 IPPS/LTCH PPS final rule (87 FR 49081 through 49094) continue to apply. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. Table I.G.7.-01 and the analysis in this proposed rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2019 and June 30, 2022 (that is, the FY 2024 Hospital Readmissions Reduction Program's applicable period, which is the most recently available data at the time of publication of this proposed rule).[874]

[874] Although the FY 2024 performance period is July 1, 2019 through June 30, 2022, we note that first and second quarter data from CY 2020 is excluded from program calculations due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments will be adjusted to July 1, 2019 through December 1, 2019 and July 1, 2020 through June 30, 2022.

Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In the FY 2025 IPPS/LTCH PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2025 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2020 through June 30, 2023).

The results in Table I.G.7.–01 include 2,855 non-Maryland hospitals estimated as eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2020 and June 30, 2023. The second column in Table I.G.7.–01 indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in Table I.G.8.–01 indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 78.53 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 87.63 percent of eligible hospitals with fewer than 100 residents and 90.29 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in Table I.G.7.–01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.7.–01 also shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2021, through September 30, 2022 (FY 2022). For example, the penalty as a share of payments for non-teaching hospitals is 0.49 percent. This means that total penalties for all non-teaching hospitals are 0.49 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

Table I.G.7.-01 Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2025 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a share of payments[d] (%)**
All Hospitals	2,855	2,356	82.52	0.44
By Geographic Location[e] (n= 2,852)				
Urban hospitals	2,172	1,836	84.53	0.44
1-99 beds	499	329	65.93	0.45
100-199 beds	630	556	88.25	0.49
200-299 beds	394	359	91.12	0.49
300-399 beds	279	257	92.11	0.47
400-499 beds	118	105	88.98	0.49
500 or more beds	252	230	91.27	0.36
Rural hospitals	680	518	76.18	0.42
1-49 beds	325	225	69.23	0.30
50-99 beds	192	150	78.13	0.39
100-149 beds	85	73	85.88	0.50
150-199 beds	45	40	88.89	0.39
200 or more beds	33	30	90.91	0.51
By Teaching Status[f] (n= 2,852)				
Non-teaching	1,677	1,317	78.53	0.49
Fewer than 100 Residents	897	786	87.63	0.45
100 or more Residents	278	251	90.29	0.39
By Ownership Type (n= 2,852)				
Government	399	313	78.45	0.33
Proprietary	663	527	79.49	0.55
Voluntary	1,790	1,514	84.58	0.44
By Safety-Net Status[g] (n= 2,852)				
Safety-net hospitals	557	469	84.20	0.37
Non-safety-net hospitals	2,295	1,885	82.14	0.46
By Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 2,852)				
0-24	1,148	901	78.48	0.52
25-49	1,412	1,208	85.55	0.41
50-64	182	157	86.26	0.31
65 and over	110	88	80.00	0.40
By Medicare Cost Report (MCR) Percentage[i] (n= 2,849)				
0-24	816	691	84.68	0.35

25-49	1,884	1,551	82.32	0.47
50-64	134	98	73.13	0.83
65 and over	15	12	80.00	0.27
By Region (n= 2,854)				
New England	122	111	90.98	0.70
Middle Atlantic	317	276	87.07	0.51
East North Central	454	386	85.02	0.45
West North Central	231	175	75.76	0.25
South Atlantic	484	430	88.84	0.48
East South Central	250	204	81.60	0.49
West South Central	440	348	79.09	0.40
Mountain	212	154	72.64	0.32
Pacific	344	271	78.78	0.34

Source: The table results are based on the data used to calculate the FY 2024 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2024 payment adjustment factors are based on discharges from July 1, 2019, through December 1, 2019, and July 1, 2020, through June 30, 2022. The shortened data period is due to the COVID-19 public health emergency (PHE) nationwide Extraordinary Circumstances Exception (ECE) which excluded data from January 1, 2020, through June 30, 2020, from the Hospital Readmissions Reduction Program calculations. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2023 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the multi-year performance period. Hospital characteristics are from the FY 2024 IPPS Proposed Rule Impact File.

For the FY 2024 applicable period, CMS will only be assessing data from July 1, 2019, through December 1, 2019, and July 1, 2020, through June 30, 2022, due to the COVID-19 PHE nationwide ECE which excluded data from January 1, 2020, through June 30, 2020, from the Hospital Readmissions Reduction Program calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2021, through September 30, 2022 (FY 2022), are used to estimate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership type, safety net status, and DSH patient percentage (n=2,852; missing=3), region (n=2,854; missing=1), and MCR percentage (n=2,849; missing=6).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2025 HOSPITAL VBP PROGRAM			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:			
	All Hospitals	**2,474**	**0.136%**
	Urban Area	1,962	0.058%
	Rural Area	512	0.436%
	Missing	.	.
	Urban Hospitals	**1,962**	**0.058%**
	0-99 beds	338	0.594%
	100-199 beds	608	0.153%
	200-299 beds	390	-0.126%
	300-499 beds	386	-0.195%
	500 or more beds	240	-0.228%
	Rural Hospitals	**512**	**0.436%**
	0-49 beds	190	0.748%
	50-99 beds	171	0.371%
	100-149 beds	80	0.284%
	150-199 beds	42	-0.062%
	200 or more beds	29	-0.090%
BY REGION:			
	Urban By Region	**1,962**	**0.058%**
	New England	100	0.089%
	Middle Atlantic	250	-0.150%
	South Atlantic	362	0.103%
	East North Central	317	0.098%
	East South Central	106	-0.200%
	West North Central	126	0.266%
	West South Central	236	-0.139%
	Mountain	148	0.083%
	Pacific	317	0.261%
	Rural By Region	**512**	**0.436%**
	New England	19	0.630%
	Middle Atlantic	36	0.164%
	South Atlantic	78	0.377%
	East North Central	97	0.478%
	East South Central	91	0.171%
	West North Central	67	0.801%

	West South Central	71	0.243%
	Mountain	30	0.802%
	Pacific	23	0.821%
BY MCR PERCENT:			
	0-25	755	0.024%
	25-50	1,634	0.173%
	50-65	84	0.434%
	Over 65	1	-0.866%
	Missing	.	.
BY DSH PERCENT:			
	0-25	912	0.363%
	25-50	1,311	0.038%
	50-65	153	-0.168%
	Over 65	98	-0.174%
	Missing	.	.
BY TEACHING STATUS:			
	Non-Teaching	1,327	0.299%
	Teaching	1,147	-0.052%

The actual FY 2025 program year's TPSs would not be reviewed and corrected by hospitals until after the FY 2025 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2024 program year would be used for the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2025 are not finalized.

7. Effects of Requirements Under the HAC Reduction Program for FY 2025

We are presenting the estimated impact of the FY 2025 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic based on previously adopted policies for the program. We are not proposing to add or remove any measures from the HAC Reduction Program in this proposed rule, nor are we proposing any changes to reporting or submission requirements which would have any significant economic impact for the FY 2025 program year or future years. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from January 1, 2021 through June 30, 2022 and version 13.0 of the PSI software. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the CDC's National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2022 and December 31, 2022. Hospital characteristics are based on the FY 2024 IPPS Final Rule Impact File.

This table includes 2,945 non-Maryland hospitals with an estimated FY 2025 Total HAC Score based on the most recently available data at the time of publication of this proposed rule. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Actual results for FY 2025 will be determined in the fall of 2024 after a 30-day review and corrections period for hospitals to review their program results. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in the table indicates the estimated number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. For example, with regard to teaching status, 448 hospitals out of 1,719 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 193 out of 933 hospitals with fewer than 100 residents and 84 out of 279 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the estimated proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2025 HAC Reduction Program. For example, 26.1 percent of the 1,719 hospitals characterized as non-teaching hospitals, 20.7 percent of the 933 teaching hospitals with fewer than 100 residents, and 30.1 percent of the 279 teaching hospitals with 100 or more residents would be subject to a payment reduction.

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2025 HAC Reduction Program (by Hospital Characteristic)			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-Performing Quartile[b]**
All Hospitals[c]	2,945	736	25.0
By Geographic Location (n = 2,931)[d]			
Urban hospitals	**2,286**	**509**	**22.3**
1-99 beds	572	143	25.0
100-199 beds	657	154	23.4
200-299 beds	406	74	18.2
300-399 beds	279	49	17.6
400-499 beds	120	36	30.0
500 or more beds	252	53	21.0
Rural hospitals	**645**	**216**	**33.5**
1-49 beds	292	89	30.5
50-99 beds	190	76	40.0
100-149 beds	86	23	26.7
150-199 beds	46	17	37.0
200 or more beds	31	11	35.5
By Teaching Status[g] (n =2,931)[d]			
Non-teaching	1,719	448	26.1
Fewer than 100 residents	933	193	20.7
100 or more residents	279	84	30.1
By Ownership[h] (n = 2,930)			
Government	397	132	33.2
Proprietary	704	146	20.7
Voluntary	1,829	447	24.4
By Safety-Net Status[e] (n = 2,931)[d]			
Safety-net	594	170	28.6
Non-safety net	2,337	555	23.7
By Disproportionate Share Hospital (DSH) Patient Percentage[f] (n = 2,931)[d]			
0-24	1,154	250	21.7
25-49	1,446	371	25.7
50-64	196	55	28.1
65 and over	135	49	36.3
By Medicare Cost Report (MCR) Percentage[i] (n = 2,924)			
0-24	901	203	22.5
25-49	1,892	480	25.4
50-64	117	33	28.2
65 and over	14	6	42.9
By Region (n= 2,945)			
New England	128	40	31.3
Middle Atlantic	324	84	25.9
East North Central	464	131	28.2
West North Central	235	49	20.9
South Atlantic	491	111	22.6
East South Central	248	70	28.2
West South Central	452	108	23.9
Mountain	224	52	23.2
Pacific	379	91	24.0

Source: FY 2025 HAC Reduction Program estimated proposed rule results are based on CMS PSI 90 data from January 1, 2021, through June 30, 2022, and CDC NHSN HAI results from January 1, 2022, through December 31, 2022. Hospital Characteristics are based on the FY 2024 IPPS Final Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a Total HAC Score (N = 2,945). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status. (n = 2,931).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 2,930)

[i] Not all hospitals had data for MCR percent (n = 2,924).

10. Effects of the Implementation of the Rural Community Hospital Demonstration Program in FY 2025

In section V.N.2 of the preamble of this proposed rule for FY 2025, we discussed our budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–260 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2025 is $49,522,206, which we are proposing as the budget neutrality offset adjustment for FY 2025. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the IPPS/LTCH PPS final rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the IPPS/LTCH PPS final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2018 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS/LTCH PPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we will continue this general procedure. At this time, for the FY 2025 IPPS/LTCH PPS proposed rule, not all of the finalized cost reports are available for the 26 hospitals that completed cost report periods beginning in FY 2019 under the demonstration payment methodology. If all of these cost reports are available, we will include in the budget neutrality offset amount in the FY 2025 IPPS/LTCH PPS final rule the amount by which the actual costs of the demonstration, as determined from these cost reports, differed from the estimated costs identified in the FY 2019 IPPS/LTCH PPS final rule.

11. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

As described in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), CMS waived certain Medicare rules for CAHs participating in the demonstration extension period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), section 129 of Public Law 116–159, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services.

As explained in the FY 2024 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration extension period of performance in the FY 2024 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2024 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110 275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2024 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2024 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2024 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2024 IPPS/LTCH PPS final rule, we finalized a policy to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period. As stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59119 through 59122), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used

to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2025. This policy will have no impact for any national payment system for FY 2025.

12. Effects of Proposed Implementation of the Transforming Episode Accountability Model (TEAM)

In section X.A. of the preamble of this proposed rule, we are proposing to test a new mandatory episode-based payment model titled the Transforming Episode Accountability Model (TEAM) under the authority of the CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center). Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM would test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM would benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare fee-for-service (FFS) payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

As proposed, TEAM would be mandatory for acute care hospitals located within selected CBSAs. This episode-based payment model would begin on January 1, 2026, and end on December 31, 2030. Payment approaches that hold providers accountable for episode cost and performance can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. TEAM could enable hospitals to consider the most appropriate strategies for care redesign, including (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating care across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

Under this proposed model, TEAM participants would continue to bill Medicare under the traditional FFS system for items and services furnished to Medicare FFS beneficiaries. The TEAM participant may receive a reconciliation payment from CMS if Medicare FFS expenditures for a performance year are less than the reconciliation target price, subject to a quality adjustment. TEAM would not have downside risk for Track 1 and TEAM participants would only be accountable for performance year spending below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount. For Track 2 and Track 3, TEAM would be a two-sided risk model that requires TEAM participants to be accountable for performance year spending above or below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount or a repayment amount.

a. Effects on the Medicare Program

TEAM is a mandatory episode-based payment model which would have a direct effect on the Medicare program because TEAM participants would be incentivized to reduce Medicare spending. Additionally, TEAM participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. Table I.G.12–01 shows the projected financial impacts of TEAM over the course of the five-year model test. The first performance year (2026) of TEAM is expected to cost the Medicare program $27 million because we assume most TEAM participants would elect participation in Track 1, which is not subject to downside risk. Therefore, the estimated $85 million represents the difference between reconciliation payment amounts and repayment amounts resulting in more TEAM participants earning reconciliation payment amounts in performance year 1 rather than paying CMS repayment amounts. In performance year 2 (2027), TEAM participants would be subject to both upside and downside risk, regardless of participation track, and we estimate TEAM participants on net (that is, repayment amounts less reconciliation payments) would pay $98 million to CMS, and that TEAM would save the Medicare program $157 million. To protect TEAM participants from significant financial risk, we have proposed a 10 percent stop-loss and stop-gain limit for TEAM participants in Track 2 and a 20 percent stop-loss and stop-gain limit for TEAM participants in Track 3. These limits would cap the total amount of repayments paid by TEAM participants to CMS or cap the total amount of reconciliation payment amounts paid by CMS to TEAM participants. In performance year 3 (2028), we estimate TEAM participants on net would pay $133 million to CMS, and that TEAM would save the Medicare program $194 million. We estimate that TEAM participants on net would pay CMS $136 million in performance year 4 and $121 million in performance year 5, and that TEAM would save the Medicare program $197 million and $184 million for these performance years, respectively. We estimate that on net, TEAM participants would pay CMS $403 million, and that TEAM would save the Medicare program approximately $705 million over the 5 performance years (2026 through 2030).

TABLE I.G.12.-01: PROJECTED FINANCIAL IMPACTS OF TEAM (IN MILLIONS)

	2026	2027	2028	2029	2030
TEAM episode spending	$5,729	$5,842	$5,958	$6,073	$6,179
(+) Reconciliation payment amounts (positive) and Repayment amounts (negative)	$85	-$98	-$133	-$136	-$121
- Baseline episode spending	$5,787	$5,902	$6,018	$6,134	$6,241
Impact	$27	-$157	-$194	-$197	-$184
Impact as % of Baseline	**0.5%**	**-2.7%**	**-3.2%**	**-3.2%**	**-2.9%**

(1) Assumptions

We assumed TEAM episode volume is estimated to grow at the same rate as projected Medicare FFS enrollment as indicated in the 2023 Medicare Trustees Report.[875] Further, an internal sample set of hospitals was used to estimate financial impacts and simulate TEAM participation. The amount of national episode spending

[875] *https://www.cms.gov/oact/tr/2023.*

captured by the sample set of hospitals was 29 percent in 2023.

We note that TEAM participants are estimated to reduce episode spending by 1 percent as a result of participating in TEAM. The fifth annual evaluation report of the Comprehensive Care for Joint Replacement (CJR) model indicated that CJR resulted in roughly a 4 percent reduction in lower extremity joint replacement (LEJR) spending (not including reconciliation payments) for participants over the course of the model.[876] Since participation in CJR is mandatory in 34 metropolitan statistical areas, and LEJR episodes make up a significant portion of the episodes included in TEAM, the CJR evaluation results appear to be a reasonable proxy for what to expect in TEAM. However, the episode length in CJR is 90 days, whereas in TEAM the proposed length is 30 days. Internal analysis indicated that the 30-day episode is approximately 75 percent as costly as a 90-day episode for LEJR procedures. In addition, post-acute care spending has been declining in recent years for episodes that we are proposing to include in TEAM, which could limit the potential for TEAM participants to achieve significant improvements in efficiency. Thus, we believe that the intervention effect of TEAM on episode spending will be a reduction of 0 to 3 percent (see Table I.G.12–02 for a sensitivity analysis for how the financial impact is affected by changes in this assumption).

We also note that starting from actual episode spending that occurred in the first half 2023, average baseline spending per episode is estimated to increase by 1.5 percent every year. The national average per episode spending growth for all TEAM episode types in years 2018, 2019, 2022, and 2023 was approximately 1.3 percent. Annual growth rates for each episode type were weighted by spending, and historical experience during 2020 and 2021 were excluded due to possible impacts from the peak of the COVID–19 pandemic. Since some of the historical experience in these years includes Medicare policy changes for LEJR episodes that resulted in surgeries occurring in more efficient care settings, translating to spending decreases that may not be duplicated in future years, the assumed annual trend is slightly greater than the observed average trend from the historical experience.

Additionally, our estimates do not include the impact of TEAM beneficiary overlap with total cost of care models, such as when a TEAM beneficiary is also assigned to a Medicare Shared Savings Program ACO. However, given the precision in the Shared Savings Program projections, we do not anticipate a practical difference in the ACO's shared savings estimates. Nor do we anticipate TEAM beneficiary overlap with total cost of care models having a meaningful effect to TEAM's projected financial impacts, described in Table I.G.12–01.

Because the financial impact is based on projections of spending, the estimates implicitly assume that there will be no significant difference between the projected episode spending used to calculate the prospective target prices and actual episode spending. This assumption has a large degree of uncertainty, and the actual TEAM financial impacts will be highly sensitive to this difference. The direction, magnitude and timing of projection inaccuracies would all affect the overall financial impact estimate.

(2) Sensitivity Analysis

We also performed a sensitivity analysis to assess various intervention effects on TEAM. Overall financial impacts are sensitive to the intervention effect TEAM would have on TEAM participants' episode spending. Table I.G.12–02 includes financial impacts at various intervention effect assumptions (note that negative values indicate savings):

TABLE I.G.12-02: TEAM SENSITIVITY ANALYSIS AT VARIOUS INTERVENTION EFFECTS

Intervention Effect	2026	2027	2028	2029	2030
-3.0%	-0.7%	-2.7%	-4.3%	-4.3%	-3.5%
-1.0%	**0.5%**	**-2.7%**	**-3.2%**	**-3.2%**	**-2.9%**
0.0%	1.1%	-2.7%	-2.7%	-2.7%	-2.7%

The sensitivity is due to the lack of the requirement that participants participate in downside risk during performance year 1 and the effect that reductions in episode spending during performance years would have on target prices for future performance years.

b. Effects on the Medicare Beneficiaries

We believe that episode-based payment models may have the potential to benefit beneficiaries because the intent of the models is to test whether providers are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery and incentivize higher value care across the inpatient and post-acute care spectrum. We believe that episode-based payment models have a patient-centered focus such that they incentivize improved healthcare delivery and communication based on the needs of the beneficiary, thus potentially benefitting beneficiaries. The proposed model would not affect beneficiary cost sharing for items and services that beneficiaries receive from TEAM participants or premiums paid by beneficiaries. If there is a shift in the utilization of items and services within each episode, then beneficiary cost sharing could be higher or lower than would otherwise be experienced.

We are proposing to include a patient reported outcome measure, specific to LEJR episode categories, in the TEAM quality measures that would be tied to payment with the belief that doing so would encourage TEAM participants to focus on and deliver improved quality of care for Medicare beneficiaries. Additionally, TEAM participants must perform well on quality measure performance to achieve their maximum reconciliation payment. The accountability of TEAM participants for both quality and the cost of care that is furnished to TEAM beneficiaries within an episode provides TEAM participants with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the proposed model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program as guaranteed under section 1802 of the Act. Eligible beneficiaries who receive one of the five proposed surgical episode categories from a TEAM participant would not have the option to opt their episodes out of the model. TEAM participants may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality, and we have proposed to use our existing authority, if necessary, to audit TEAM participants if claims analysis indicates an inappropriate change in delivered services. Given that TEAM participants would receive a reconciliation payment, subject to a quality adjustment, when they are able to reduce spending below the reconciliation target price, they could have an incentive to avoid complex, high-cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from TEAM participants—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also proposed to require TEAM participants to supply beneficiaries with written information

[876] *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-annual-report.*

regarding the hospital's participation in TEAM as well as their rights under Medicare, including their right to use their provider of choice.

We have proposed to implement safeguards to ensure that Medicare beneficiaries do not experience a delay in services. Specifically, to avoid perverse incentives to withhold or delay medically necessary care until after an episode ends, we propose that TEAM participants remain responsible for episode spending in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed episode definition.

Importantly, approaches to savings will include taking steps that facilitate patient recovery, shorten recovery duration, and minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

Lastly, we note that the proposed TEAM Model would not change Medicare FFS payments, beneficiary copayments, deductibles, or coinsurance. Beneficiaries may benefit if TEAM participants are able to systematically improve the quality of care while reducing costs. We welcome public comments on our estimates of the impact of our proposals on Medicare beneficiaries.

c. Aggregate Effects on the Market

There may be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model, if finalized. Testing changes in Medicare payment policy may have implications for non-Medicare payers. As an example, non-Medicare patients may benefit if participating hospitals introduce system-wide changes that improve the coordination and quality of health care. Other payers may also be developing payment models and may align their payment structures with CMS or may be waiting to utilize results from CMS' evaluations of payment models. Because it is unclear whether and how this evidence applies to a test of these new payment models, our analyses assume that spillover effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We welcome comments on this assumption and evidence on how this rulemaking, if finalized, would impact non-Medicare payers and patients.

13. Effects of Proposed Changes the Provider Reimbursement Review Board (PRRB) Membership

In section X.B of the preamble of this proposed rule, we are proposing changes to 42 CFR 405.1845 to permit individuals to serve one or two additional consecutive terms as PRRB Members, relative to the current regulations, which allow two consecutive 3-year terms (6 consecutive years). Based on historical experience, PRRB Members generally serve 6 consecutive years as permitted by the current regulations; under the proposed rule, a PRRB Member would be eligible to serve for 9 years, or 12 years if they are designated as Chairperson in their second or third consecutive term. We anticipate achieving productivity gains and greater efficiencies from retaining experienced Board Members over a longer period, particularly since Board Members spend a portion of their initial term acclimating to the adjudicatory responsibilities and deepening their expertise in the wide scope of specialized matters that come before the Board. Accordingly, under this proposal, we anticipate that a Board Member could address increasingly complex and technical issues and a higher volume of cases as they gain additional seniority. Furthermore, providing an individual the opportunity to experience the day-to-day responsibilities of the PRRB before leading the Board as Chairperson could benefit the entire five-person Board. Finally, the possibility of having a 9-to-12-year tenure on the PRRB might make the position more attractive to prospective applicants, thereby increasing the size of the candidate pool. We believe for example that otherwise qualified individuals might refrain from applying, knowing that the position is limited to no more than 6 years. Therefore, these proposed changes will result in a no cost impact relative to the requirements of Executive Orders 12866, 13563, and 14094. There may be negligible government savings attributable to reducing human resource-related costs such as recruitment and hiring activity.

14. Effects of the Proposed Removal of the Puerto Rico Exclusion From Payment Error Rate Measurement (PERM) Review

In section X.E. of the preamble of this proposed rule, we discuss in detail the changes to the administration of the existing PERM program. The Further Consolidated Appropriations Act of 2020 (Pub. L. 116–94) required Puerto Rico to publish a plan, developed in coordination with CMS, and approved by the CMS Administrator, not later than 18 months after the FCAA's enactment, for how Puerto Rico would develop measures to comply with the PERM requirements of 42 CFR part 431, subpart Q. Currently, Puerto Rico is excluded from PERM via regulation at 42 CFR 431.954(b)(3). Puerto Rico would be incorporated into the PERM program starting in reporting year 2027 (Cycle 3), which covers the payment period between July 1, 2025 through June 30, 2026.

Including Puerto Rico in the PERM program would increase visibility into its Medicaid and CHIP operations and should improve program integrity efforts that protect taxpayer dollars from improper payments. A state[877] in the PERM program will be reviewed only once every 3 years and it is not likely that a provider would be selected more than once per program cycle to provide supporting documentation, minimizing the annual burden on both the state and its providers. Therefore, we estimate the cost to Puerto Rico for participating in the PERM program would be approximately $3.5 million annually. More detail about the cost and burden hours associated with response to requests for information (approximately 6,000 hours annually) can be found in the program PRA package (CMS–10166, CMS–10178, CMS–10184). Therefore, we do not anticipate this to be a significant administrative cost.

We are not preparing an analysis for this policy under the Regulatory Flexibility Act (RFA) because we have determined that the policy will not have a significant impact on a substantial number of small entities.

We are not preparing an analysis for section 1102(b) of the Act because this policy will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $183 million. This policy will not result in an impact of $183 million or more on State, local or tribal governments, in the aggregate, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this policy does not impose substantial costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

14. Effects of Hospital and CAH Reporting of Acute Respiratory Illnesses

In section X.F. of the preamble of this proposed rule, we discuss our proposed requirements related to the reporting of acute respiratory illnesses that would have potentially major public health benefits. Proposed routine reporting of these illnesses absent any new emergency makes it possible to use the data to determine which hospitals faced unusually high or low reported levels of such illnesses. Such comparisons would allow individual hospitals, individual cities or states, or the federal government, to analyze outlier hospitals (either high or low rates of acute respiratory infections) to determine if there were any local factors that might suggest some form of intervention would be beneficial to redress problems or to export successes among the universe of hospitals and CAHs. For example, if hospitals in a particular geographic area were finding an unusually high rate of these illnesses among admitted patients from a particular geographic area, investigation of potential causes might lead to improvements in that area's immunization outreach efforts. It would not take many such interventions to have potentially substantial life-saving effects. Since the value of a ''statistical'' human life saved is generally estimated by HHS to have a value of about $10 million, even a dozen lives saved somewhere in the nation would exceed the cost of this reporting several times over.[878] In the

[877] For PERM, a ''state'' represents an entity receiving Medicaid and CHIP funding that is measured for improper payments, which includes the 50 states, the District of Columbia, and now Puerto Rico.

[878] See the discussion of assessing benefits in the HHS Guidelines for Regulatory Impact Analysis at *https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.*

hopefully unlikely case where an outbreak of acute respiratory illness was so substantial as to require the declaration of a public health emergency, the life-saving benefits could be many times higher. For example, an ''early warning'' signal could speed the development of a vaccine, effective use of particular medicines for treatments, or other interventions to prevent or ameliorate adverse outcomes ranging from a single instance of illness to a national epidemic.

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of January 2024, there were 91 children's hospitals, 11 cancer hospitals, 6 short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 1 extended neoplastic disease care hospital, and 9 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the changes on LTCHs are discussed in section I.J. of this appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2025 percentage increase in the 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket increase, we are estimating the FY 2025 update to be 3.0 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this proposed rule. We proposed that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2025. The Affordable Care Act requires a productivity adjustment (0.4 percentage point reduction proposed for FY 2025), resulting in a proposed 2.6 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.B. of the preamble of this proposed rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2018-based IPPS operating market basket for FY 2025, currently estimated at 3.0 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section of this proposed rule, we used data from the December 2023 update of the FY 2023 MedPAR file and the December 2023 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2023 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of this proposed rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2023 update of the FY 2023 MedPAR file, we simulated payments under the capital IPPS for FY 2024 and the proposed payments for FY 2025 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2025 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 3.0 percent for FY 2025.
- In addition to the proposed FY 2025 update factor, the proposed FY 2025 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9994, a proposed budget neutrality factor for the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy of 0.9943, and a proposed outlier adjustment factor of 0.9577.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of the proposed changes for FY 2025 on total capital payments per case, using a universe of 3,090 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2023 update of the FY 2023 MedPAR file, the December 2023 update to the PSF, and the most recent available cost report data from the December 2023 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2024 and estimated proposed total payments per case for FY 2025 based on the proposed FY 2025 payment policies. Column 2 shows estimates of payments per case under our model for FY 2024. Column 3 shows estimates of proposed payments per case under our model for FY 2025. Column 4 shows the total proposed percentage change in payments from FY 2024 to FY 2025. The change represented in Column 4 includes the proposed 3.0 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2025 are expected to increase 2.4 percent compared to capital payments per case in FY 2024. This expected increase is primarily due

to the proposed 3.0 percent update to the capital Federal rate being partially offset by an expected decrease in capital outlier payments. In general, regional variations in estimated capital payments per case in FY 2025 as compared to capital payments per case in FY 2024 are primarily due to the proposed changes in GAFs, and are generally consistent with the projected changes in payments due to the proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.F. of this appendix.

The net impact of these proposed changes is an estimated 2.4 percent increase in capital payments per case from FY 2024 to FY 2025 for all hospitals (as shown in Table III). The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2025 as compared to FY 2024. Capital IPPS payments per case would increase by an estimated 2.4 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 3.4 percent from FY 2024 to FY 2025. The primary factor contributing to the difference in the projected increase in capital IPPS payments per case for rural hospitals as compared to urban hospitals is the estimated increase in capital payments to rural hospitals due to the effect of proposed changes in the GAFs.

The comparisons by region show that the change in capital payments per case from FY 2024 to FY 2025 for urban areas range from a 0.1 percent decrease for the New England urban region to a 5.2 percent increase for the East South Central urban region. Meanwhile, the change in capital payments per case from FY 2024 to FY 2025 for rural areas range from a 1.0 percent increase for the Pacific rural region to a 5.4 percent increase for the East South Central rural region. Capital IPPS payments per case for hospitals located in Puerto Rico are projected to increase by an estimated 2.3 percent. These regional differences are primarily due to the proposed changes in the GAFs.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that both proprietary and government hospitals are expected to experience an increase in capital payments per case from FY 2024 to FY 2025 of 2.6 percent. Meanwhile, voluntary hospitals are expected to experience an increase in capital payments per case from FY 2024 to FY 2025 of 2.4 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2025. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2025, we show the proposed average capital payments per case for reclassified hospitals for FY 2025. Urban reclassified hospitals are expected to experience an increase in capital payments of 2.4 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.3 percent. Rural reclassified hospitals are expected to experience an increase in capital payments of 3.9 percent; rural nonreclassified hospitals are expected to experience an increase in capital payments of 2.6 percent. The higher expected increase in payments for rural reclassified hospitals compared to rural nonreclassified hospitals is primarily due to the proposed changes in the GAFs.

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TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2024 PAYMENTS COMPARED TO PROPOSED FY 2025 PAYMENTS]	Number of Hospitals	Average FY 2024 Payments/Case	Proposed Average FY 2025 Payments/Case	Change
All Hospitals	3,090	1,157	1,185	2.4
By Geographic Location:				
Urban hospitals	2,390	1,191	1,219	2.4
Rural hospitals	700	792	819	3.4
Bed Size (Urban):				
0-99 beds	643	894	913	2.1
100-199 beds	683	983	1,005	2.2
200-299 beds	418	1,096	1,120	2.2
300-499 beds	397	1,186	1,213	2.3
500 or more beds	247	1,425	1,462	2.6
Bed Size (Rural):				
0-49 beds	350	666	688	3.3
50-99 beds	183	759	779	2.6
100-149 beds	92	766	791	3.3
150-199 beds	44	861	893	3.7
200 or more beds	31	968	1,009	4.2
Urban by Region:				
New England	106	1,259	1,258	-0.1
Middle Atlantic	280	1,361	1,381	1.5
East North Central	367	1,086	1,121	3.2
West North Central	156	1,124	1,164	3.6
South Atlantic	396	1,037	1,066	2.8
East South Central	141	983	1,034	5.2
West South Central	357	1,069	1,116	4.4
Mountain	178	1,195	1,211	1.3
Pacific	358	1,573	1,589	1.0
Rural by Region:				
New England	21	1,050	1,092	4.0
Middle Atlantic	53	891	925	3.8
East North Central	111	768	792	3.1
West North Central	79	784	811	3.4
South Atlantic	112	735	749	1.9
East South Central	134	722	761	5.4
West South Central	124	699	729	4.3
Mountain	42	868	881	1.5
Pacific	24	1,069	1,080	1.0
Puerto Rico:				
Puerto Rico Hospitals	51	620	634	2.3
By Payment Classification:				
Urban hospitals	1,705	1,104	1,130	2.4
Rural areas	1,385	1,206	1,237	2.6
Teaching Status:				
Nonteaching	1,843	946	967	2.2
Fewer than 100 residents	959	1,081	1,109	2.6
100 or more residents	288	1,569	1,606	2.4
Urban DSH:				
Non-DSH	325	997	1,022	2.5
100 or more beds	1,009	1,141	1,168	2.4
Less than 100 beds	371	816	831	1.8
Rural DSH:				
Non-DSH	96	1,097	1,115	1.6
SCH	248	822	845	2.8
RRC	791	1,254	1,285	2.5

[FY 2024 PAYMENTS COMPARED TO PROPOSED FY 2025 PAYMENTS]	Number of Hospitals	Average FY 2024 Payments/Case	Proposed Average FY 2025 Payments/Case	Change
100 or more beds	41	1,180	1,225	3.8
Less than 100 beds	209	662	685	3.5
Urban teaching and DSH:				
Both teaching and DSH	579	1,208	1,237	2.4
Teaching and no DSH	54	1,050	1,077	2.6
No teaching and DSH	801	991	1,012	2.1
No teaching and no DSH	271	966	990	2.5
Special Hospital Types:				
RRC	142	893	927	3.8
RRC with Section 401 Rural Reclassification	586	1,313	1,344	2.4
SCH	249	766	784	2.3
SCH with Section 401 Rural Reclassification	38	953	980	2.8
SCH and RRC	120	868	901	3.8
SCH and RRC with Section 401 Rural Reclassification	43	1,107	1,138	2.8
Type of Ownership:				
Voluntary	1,911	1,158	1,186	2.4
Proprietary	753	1,060	1,088	2.6
Government	425	1,273	1,306	2.6
Medicare Utilization as a Percent of Inpatient Days:				
0-25	1,362	1,248	1,281	2.6
25-50	1,623	1,091	1,116	2.3
50-65	65	1,045	1,059	1.3
Over 65	17	716	721	0.7
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	1,955	1,056	1,082	2.5
25-50	1,009	1,298	1,330	2.5
50-65	97	1,538	1,554	1.0
Over 65	29	1,564	1,581	1.1
FY 2025 Reclassifications:				
All Reclassified Hospitals	1,141	1,208	1,238	2.5
Non-Reclassified Hospitals	1,949	1,098	1,124	2.4
Urban Hospitals Reclassified	965	1,248	1,278	2.4
Urban Non-Reclassified Hospitals	1,438	1,115	1,141	2.3
Rural Hospitals Reclassified Full Year	294	804	835	3.9
Rural Non-Reclassified Hospitals Full Year	393	773	793	2.6
All Section 401 Rural Reclassified Hospitals	741	1,281	1,312	2.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	797	822	3.1

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J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2025. In the preamble of this proposed rule, we specify the statutory authority for the proposals that are presented, identify the proposed policies for FY 2025, and present rationales for our proposals as well as alternatives that were considered. In this section, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 330 LTCHs included in this impact analysis. We note that, although there are currently approximately 338 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2025 MS–LTC–DRG relative weights (discussed in section VIII.B.3. of the preamble of this proposed rule). We have also excluded data for CCN 312024 from this impact analysis due to their abnormal charging practices. We note this is consistent with our proposals to remove this LTCH from the calculation of the FY 2025 MS–LTC–DRG relative weights, the area wage level adjustment budget neutrality factor, and the fixed-loss amount for LTCH PPS standard Federal payment rate cases (discussed in section VIII.B.3. of the preamble of this proposed rule). Moreover, another LTCH, only had one claim in the claims data used for this proposed rule. Because the number of covered days of care that are chargeable to Medicare utilization for the stay was reported as 0 on this claim, we excluded this claim and LTCH from our impact analysis. Lastly, in the claims data used for this proposed rule, one of the 330 LTCHs included in our impact analysis only had claims for site neutral payment rate cases and, therefore, does not affect our impact analysis for LTCH PPS standard Federal payment rate cases presented in Table IV (that is, the impact analysis presented in Table IV is based on the data for 329 LTCHs).

In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values (including the proposed update to the CBSA labor market areas) and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2025.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment

rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases.

Based on the best available data for the 330 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2025 will increase by approximately 1.6 percent (or approximately $41 million) based on the proposed rates and factors presented in section VIII. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2023 LTCH cases that were used for the analysis in this proposed rule, approximately 29 percent of those cases were classified as site neutral payment rate cases (that is, 29 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). We note that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, all LTCH PPS cases in FY 2023 with admission dates on or before the PHE expiration date were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Because not all FY 2023 cases were subject to the site neutral payment rate, for purposes of this impact analysis, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2024. Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be classified as site neutral payment rate cases in FY 2025 will not change significantly from the most recent historical data. To estimate FY 2025 LTCH PPS payments for site neutral payment rate cases, we calculated the IPPS comparable per diem amounts using the proposed FY 2025 IPPS rates and factors along with other changes that would apply to the site neutral payment rate cases in FY 2025. We estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 4.7 percent (or approximately $14 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and factors reflected in our estimate of the IPPS comparable per diem amount, as well as an increase in estimated costs for these cases determined using the proposed charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this proposed rule. We note that we estimate payments to site neutral payment rate cases in FY 2025 will represent approximately 12 percent of estimated aggregate FY 2025 LTCH PPS payments.

Based on the FY 2023 LTCH cases that were used for the analysis in this proposed rule, approximately 71 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2025, and will be paid based on the LTCH PPS standard Federal payment rate. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2025 will increase approximately 1.2 percent (or approximately $26 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2025 is primarily due to the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate being partially offset by a projected 1.3 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section.

Based on the 330 LTCHs that were represented in the FY 2023 LTCH cases that were used for the analyses in this proposed rule presented in this appendix, we estimate that aggregate FY 2024 LTCH PPS payments will be approximately $2.583 billion, as compared to estimated aggregate FY 2025 LTCH PPS payments of approximately $2.624 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $41 million. We note that the estimated $41 million increase in LTCH PPS payments in FY 2025 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the proposed policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2024 is $48,116.62. For FY 2025, we are proposing to establish an LTCH PPS standard Federal payment rate of $49,262.80 which reflects the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate and the proposed budget neutrality factor for updates to the area wage level adjustment of 0.9959347 (discussed in section V.B.6. of the Addendum to this proposed rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $48,304.38. This proposed LTCH PPS standard Federal payment rate reflects the proposed updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.8 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.7 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025, on average, for all LTCHs (Column 6). The estimated increase of 2.7 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.7 percent.

For FY 2025, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2021 which is the same data used for the FY 2025 IPPS wage index) and the revised CBSA labor market areas delineations that we are proposing to adopt (as discussed in section V.B.2. of the Addendum to this proposed rule). In addition, we are proposing to establish a labor-related share of 72.8 percent for FY 2025, based on the most recent available data (IGI's fourth quarter 2023 forecast) of the relative importance of the labor-related share of operating and capital costs of the proposed 2022-based LTCH market basket. We also are proposing to apply an area wage level budget neutrality factor of 0.9959347 to ensure that the proposed changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2024 to FY 2025. Based on the FY 2023 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2024 high-cost outlier threshold of $59,873 (as established in the FY 2024 IPPS/LTCH PPS final rule) will result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2024 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high-cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 9.3 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2024. Combined with our estimate that FY 2025 high-cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2025, this will result in an estimated decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 1.3 percent between FY 2024 and FY 2025. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2023 claims by the proposed charge inflation factor described in section V.D.3.b. of the Addendum to this proposed rule. We also note that, in calculating these estimated high-cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule. We lastly note, we are soliciting comments on our proposed methodology for determining the fixed-loss amount for FY

2025 (described in section V.D.3.b. of the Addendum to this proposed rule) as well as on an alternative approach we considered (described in section I.O.4. of this appendix). We will consider these comments when finalizing the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 in the final rule.

Table IV shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2025 by comparing estimated FY 2024 LTCH PPS payments to estimated FY 2025 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases as discussed in section I.J.3. of this appendix.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments (for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases), and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.3 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This increase is primarily due to the combination of the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate for FY 2025, the proposed changes to the area wage level adjustment, and estimated changes in outlier payments. This estimated impact is based on the FY 2023 data for the 18 rural LTCHs (out of 329 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of the Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.1. of this appendix, we project an increase in aggregate LTCH PPS payments in FY 2025 of approximately $41 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $26 million and the projected increase in payments to site neutral payment rate cases of approximately $14 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2025 LTCH PPS payments (that is, FY 2023 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2025, it is necessary to estimate payments per discharge for FY 2024 using the rates, factors, and the policies established in the FY 2024 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2025 using the proposed rates, factors, and the policies in this proposed rule (as discussed in section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our proposed policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Proposed Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2024 and proposed FY 2025 payments on a case-by-case basis using historical LTCH claims from the FY 2023 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2023 MedPAR files. For modeling FY 2024 LTCH PPS payments, we used the FY 2024 standard Federal payment rate of $48,116.62 (or $47,185.03 for LTCHs that failed to submit quality data as required under the

requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2025 LTCH PPS standard Federal payment rate, we used the proposed FY 2025 standard Federal payment rate of $49,262.80 (or $48,304.38 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable proposed adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2024 LTCH PPS payments, we used the current FY 2024 labor-related share (68.5 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2024 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2024 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $59,873 (as reflected in the FY 2024 IPPS/LTCH PPS final rule), and the FY 2024 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2024 nonlabor-related share (31.5 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling proposed FY 2025 LTCH PPS payments, we used the proposed FY 2025 LTCH PPS labor-related share (72.8 percent), the proposed FY 2025 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the proposed FY 2025 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $90,921 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2025 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2025 nonlabor-related share (27.2 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2023 claims by the proposed charge inflation factors in section V.D.3.b. of the Addendum to this proposed rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2024 to FY 2025 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2024 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated proposed FY 2025 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2024 to FY 2025 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 due to the proposed changes to the area wage level adjustment (that is, the proposed updated hospital wage data, the proposed labor market areas, and the proposed labor-related share) and the application of the corresponding proposed budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 (Column 4) to FY 2025 (Column 5) due to all proposed changes.

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TABLE IV: IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2025 (ESTIMATED FY 2024 PAYMENTS COMPARED TO ESTIMATED FY 2025 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2024 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2025 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	329	42,036	54,275	54,905	2.7	0.0	1.2
BY LOCATION:							
RURAL	18	1,550	39,576	40,472	2.7	1.0	2.3
URBAN	311	40,486	54,838	55,457	2.7	0.0	1.1
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	926	52,855	52,108	2.8	-1.6	-1.4
OCT. 1983 - SEPT. 1993	36	5,151	62,934	63,747	2.6	0.2	1.3
OCT. 1993 - SEPT. 2002	130	17,117	53,272	53,960	2.7	0.1	1.3
AFTER OCTOBER 2002	153	18,842	52,890	53,483	2.7	-0.1	1.1
BY OWNERSHIP TYPE:							
VOLUNTARY	52	4,869	57,755	57,864	2.7	-0.1	0.2
PROPRIETARY	267	36,587	53,490	54,202	2.7	0.0	1.3
GOVERNMENT	10	580	74,621	74,382	2.7	-0.8	-0.3
BY REGION:							
NEW ENGLAND	10	1,279	46,316	46,230	2.7	-1.2	-0.2
MIDDLE ATLANTIC	19	2,656	65,050	65,745	2.7	-0.3	1.1
SOUTH ATLANTIC	59	8,721	53,664	54,419	2.7	0.4	1.4
EAST NORTH CENTRAL	47	5,754	54,517	54,972	2.7	-0.2	0.8
EAST SOUTH CENTRAL	31	3,034	50,006	50,805	2.7	0.8	1.6
WEST NORTH CENTRAL	21	2,247	48,603	48,971	2.7	-0.1	0.8
WEST SOUTH CENTRAL	92	10,765	46,990	47,700	2.7	0.3	1.5
MOUNTAIN	27	2,163	54,639	55,848	2.7	0.3	2.2
PACIFIC	23	5,417	70,677	71,048	2.6	-0.8	0.5
BY BED SIZE:							
BEDS: 0-24	30	1,880	50,056	50,795	2.7	0.5	1.5
BEDS: 25-49	160	16,908	48,432	49,206	2.7	0.3	1.6
BEDS: 50-74	72	9,747	55,244	55,864	2.7	-0.1	1.1
BEDS: 75-124	46	8,411	62,276	62,925	2.7	-0.3	1.0
BEDS: 125-199	18	4,681	61,464	61,562	2.7	-0.3	0.2
BEDS: 200+	3	409	45,379	45,397	2.7	-0.5	0.0

[1] Estimated FY 2025 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 due to the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 due to the proposed changes to the area wage level adjustment under § 412.525(c) (that is, the proposed updated hospital wage data, the proposed labor market areas, and the proposed labor related share) with budget neutrality.

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 (shown in Column 4) to FY 2025 (shown in Column 5), due to all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge due to all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge due to the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and due to the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2023 LTCH cases (from 329 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 1.2 percent, on average, for all LTCHs from FY 2024 to FY 2025 as

a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 1.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2025 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2024 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this appendix).

As stated previously, we are proposing an annual update to the LTCH PPS standard Federal payment rate for FY 2025 of 2.8 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a proposed budget neutrality factor for changes to the area wage level adjustment of 0.9959347 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section of the proposed rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.7 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2024 to FY 2025. We note our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit data under the requirements of the LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 for all hospitals is 1.2 percent. Urban LTCHs are projected to experience an increase of 1.1 percent. Meanwhile, rural LTCHs are projected to experience an increase of 2.3 percent.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 45 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 of 1.3 percent and 1.1 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 of 1.3 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a decrease in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 of 1.4 percent, partially due to the proposed changes to the area wage level adjustment.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 1.3 percent. Voluntary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 of 0.2 percent. Meanwhile, government owned and operated LTCHs are expected to experience a decrease in payments to LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 of 0.3 percent.

(4) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2024 to FY 2025 are projected to range from a decrease of 0.2 percent in the New England region to an increase of 2.2 percent in the Mountain region. These regional variations are primarily due to the proposed changes to the area wage adjustment and estimated changes in outlier payments.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with greater than 200 beds will experience no change in payments for LTCH PPS standard Federal payment rate cases. LTCHs with 25–49 beds are projected to experience the largest increase in payments, 1.6 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 0.2 to 1.5 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2025 relative to FY 2024 of approximately $26 million (or approximately 1.2 percent) for the 330 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2025 relative to FY 2024 of approximately $14 million (or approximately 4.7 percent) for the 330 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2025 will represent approximately 12 percent of total estimated FY 2025 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2025 relative to FY 2024 of approximately $41 million (or approximately 1.6 percent) for the 330 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.C. of the preamble of this proposed rule, we discuss proposed requirements for hospitals reporting quality data under the Hospital IQR Program to receive the full annual percentage increase for the FY 2027 payment determination and subsequent years.

In the preamble of this proposed rule, we are proposing: (1) to adopt the Age-Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (2) to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (3) to adopt the Catheter-Associated Urinary Tract Infection (CAUTI)

Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (4) to adopt the Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 reporting period; (5) to adopt the Hospital Harm—Falls with Injury electronic clinical quality measure (eCQM) beginning with the CY 2026 reporting period/FY 2028 payment determination; (6) to adopt the Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; (7) to adopt the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination; (8) to modify the Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination; (9) to modify the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 payment determination (10) to remove the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (11) to remove the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (12) to remove the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN) measure beginning with the July 1, 2021–June 30, 2024 reporting period/FY 2026 payment determination; (13) to remove the Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2021–March 31, 2024 reporting period/FY 2026 payment determination; (14) to remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measure beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination; (15) to increase the total number of eCQMs reported from six to nine for the CY 2026 reporting period/FY 2028 payment determination and then from nine to eleven beginning with the CY 2027 reporting period/FY 2029 payment determination; (16) to update the scoring methodology for eCQM validation; (17) to remove the requirement that hospitals must submit 100 percent of eCQM records to pass validation beginning with CY 2025 eCQM data affecting the FY 2028 payment determination; and (18) to no longer require hospitals to resubmit medical records as part of their request for reconsideration of validation beginning with CY 2025 discharges affecting the FY 2028 payment determination.

As shown in the summary tables in section XII.B.6.k. of the preamble of this proposed rule, we estimate a total information collection burden increase for 3,050 IPPS hospitals of 40,019 hours at a cost of $1,274,980 annually associated with the policies we are proposing across a 3-year period from the CY 2025 reporting period/FY 2027 payment determination through the CY 2027 reporting period/FY 2029 payment determination, compared to our currently approved information collection burden estimates.

In sections IX.C.5.a. and IX.B.1 of the preamble of this proposed rule, we are proposing to adopt the Age-Friendly Hospital and Patient Safety Structural measures. In order for hospitals to receive a point for each of the domains in the measures, affirmative attestations are required for each of the statements within a domain. Similar to the FY 2023 IPPS/LTCH PPS final rule adoption of the Hospital Commitment to Health Equity measure, for hospitals that are unable to attest affirmatively for a statement and would like to earn additional points under the measure, there are likely to be additional costs associated with activities such as updating hospital policies, protocols, or processes; engaging senior leadership; conducting required analyses, surveys, and screenings; performing data analysis and collection; and training staff (87 FR 49492). The extent of these costs would vary from hospital to hospital depending on what policies the hospital already has in place, what activities the hospital is already performing, hospital size, and the individual choices each hospital makes to meet the criteria necessary to attest affirmatively. There may also be some non-recurring costs associated with changes in workflow and information systems to collect patient screening data, however the extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (for example paper-based, electronically patient-directed, clinician-facilitated, etc.).

For the Age-Friendly Hospital measure, there would be additional impacts incurred by patients admitted to hospitals that do not currently conduct patient screenings but would decide to do so. Hospitals would be able to conduct these screenings via multiple methods, however, we believe most hospitals would likely collect data through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. For the Frailty Screening and Intervention domain, we assume patients would be screened using a combination of validated tools such as the Katz Index of Independence in Activities of Daily Living, the Lawton and Brody Instrumental Activities of Daily-Living Scale, the Mini-Cog screening for early dementia, and the Patient Health Questionnaire-2 depression module.[879] [880] [881] [882] [883] For the Social Vulnerability domain, we assume patients would be screened using a tool such as the Emergency Department Senior Abuse Identification (ED Senior AID) tool,[884] which is currently undergoing validation. We estimate each patient would require no more than 20 minutes (0.33 hours) to complete the screenings for both domains.

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.04/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.[885] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $1,118 was divided by 40 hours to calculate an hourly pre-tax wage rate of $27.95/hr.[886] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[887] resulting in the post-tax hourly wage rate of $24.04/hr. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

Based on information collected by the Agency for Healthcare Research and Quality for CY 2010 through CY 2019,[888] we estimate approximately 7,600,000 patients would be screened annually across all participating IPPS hospitals (12,850,233 average annual admissions of patients aged 65 and over × (3,050 IPPS hospitals ÷ 5,157 total U.S. community hospitals [889])) or an average of 2,492 patients per IPPS hospital. For the CY 2025 reporting period and subsequent years, for each IPPS hospital that elects to perform these screenings, we estimate it would require patients an average of 831 hours (2,492 respondents × 0.33 hours) at a cost of $19,969 (831 hours × $24.04) to complete the screenings.

In sections IX.C.5.c. and IX.C.5.d. of the preamble of this proposed rule, we are proposing to adopt two new eCQMs. As noted in the FY 2019 IPPS/LTCH PPS final

[879] Park, C., et al. (2022). ''Association Between Implementation of a Geriatric Trauma Clinical Pathway and Changes in Rates of Delirium in Older Adults With Traumatic Injury.'' JAMA Surg 157(8): 676–683.

[880] *https://mini-cog.com/#:~:text=The%20Mini%2DCog%C2%A9%20is,cognitive%20impairment%20in%20older%20patients.*

[881] *https://www.physio-pedia.com/Katz_ADL#:~:text=The%20Katz%20ADL%2C%20is%20an,to%20perform%20and%20requires%20training.*

[882] *https://cde.nida.nih.gov/sites/nida_cde/files/PatientHealthQuestionnaire-2_v1.0_2014Jul2.pdf.*

[883] *https://geriatrictoolkit.missouri.edu/funct/Lawton_IADL.pdf.*

[884] Platts-Mills TF, Dayaa JA, Reeve BB, et al. Development of the Emergency Department Senior Abuse Identification (ED Senior AID) tool. J Elder Abuse Negl. Aug-Oct 2018;30(4):247–270. doi:10.1080/08946566.2018.1460285.

[885] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[886] *https://www.bls.gov/news.release/pdf/wkyeng.pdf.* Accessed January 2, 2024.

[887] *https://www.census.gov/library/stories/2023/09/median-household-income.html.* Accessed January 2, 2024.

[888] *https://datatools.ahrq.gov/hcupnet/.* Accessed January 3, 2024.

[889] *https://www.aha.org/statistics/fast-facts-us-hospitals.* Accessed January 3, 2024.

rule regarding removal of eCQMs, while there is no change in information collection burden related to the proposed policies with regard to submission of measure data, we believe that costs associated with adopting two new eCQMs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining all of the eCQMs available for use in the Hospital IQR Program in hospitals' EHR systems (83 FR 41771). We do not believe the remaining proposed policies would result in any additional economic impact beyond the additional collection of information burden discussed in section XII.B.6 of this proposed rule.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of the Hospital IQR Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years based on review of previous performance.

L. Effects of Proposed New Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D. of the preamble of this proposed rule, we discuss proposed requirements for PPS-exempt cancer hospitals (PCHs) reporting quality data under the PCH Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In the preamble of this proposed rule, we are proposing: (1) to adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year; (2) to modify the HCAHPS Survey beginning with the CY 2025 reporting period/FY 2027 program year; and (3) to move up the start date for public display of PCH performance on the Hospital Commitment to Health Equity measure.

As shown in the summary table in section XII.B.7.d. of the preamble of this proposed rule, we estimate a total information collection burden increase for 11 PCHs of 166 hours at a cost of $4,047 annually associated with our proposed policies and updated burden estimates beginning with the CY 2025 reporting period/FY 2027 program year compared with our currently approved information collection burden estimates. We refer readers to section XII.B.7. of this proposed rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the PCHQR Program.

In section IX.B.1. of the preamble of this proposed rule, we are proposing to adopt the Patient Safety Structural measure. We are proposing that in order for a PCH to receive a point for a domain in the measure, the PCH would be required to affirmatively attest to each of the statements within that domain. We estimate that if a PCH is unable to attest affirmatively to all of the statements in a domain and, in a future program year, desires to earn a point for that domain, the PCH will likely incur costs associated with activities needed to be able to affirmatively attest, which could include updating policies, protocols, or processes; engaging senior leadership; conducting required analyses; or training staff (87 FR 49492). The extent of these costs will vary from PCH to PCH depending on what policies the PCH already has in place, what activities the PCH is already performing, facility size, and the individual choices each PCH makes in order to meet the criteria necessary to attest affirmatively. We do not believe the remaining proposals to modify the HCAHPS Survey beginning with the CY 2025 reporting period/FY 2027 program year and to move up the start date for public display of PCH performance on the Hospital Commitment to Health Equity measure will result in any additional economic impact.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.E. of the preamble of the proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements under the SDOH category and to modify the current Transportation item on the LCDS beginning with the FY 2028 LTCH QRP. We are proposing to adopt items to be collected at admission using the LCDS for: Living Situation (one item), Food (two items), and Utilities (one item). We are proposing to modify the current Transportation item on the LCDS, which is currently collected at admission and discharge. We are proposing that the Transportation item would only be collected at admission beginning with the FY 2028 LTCH QRP. We are also proposing to extend the admission assessment window for the LCDS from three to four days beginning with the FY 2028 LTCH QRP. Finally, we are seeking information on two topics: future measure concepts for the LTCH QRP and a future LTCH Star Rating system.

The effect of these proposals for the LTCH QRP would be an overall increase in burden for LTCHs participating in the LTCH QRP. As shown in summary table XII.B–06 in section XII.B.7. of the preamble of this proposed rule, we estimate a total information collection burden increase for 329 eligible LTCHs of 2,116.55 hours for a cost increase of $138,231.88 annually associated with our proposed policies and updated burden estimates for the FY 2028 program year compared to our currently approved information collection burden estimates. We refer readers to section XII.B.8. of the preamble of this proposed rule, where CMS has provided an estimate of the burden and cost to LTCHs, and note that it will be included in a revised information collection request for 0938–1163.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.F. of the preamble of this proposed rule, we discuss proposed requirements for eligible hospitals and critical access hospitals (CAHs) to report objectives and measures, and report electronic clinical quality measures (eCQMs) under the Medicare Promoting Interoperability Program.

In this proposed rule, we are proposing: (1) to adopt the Hospital Harm—Falls with Injury eCQM beginning with the CY 2026 reporting period; (2) to adopt the Hospital Harm—Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period; (3) to modify the Antimicrobial Use and Resistance (AUR) Surveillance measure by splitting it into an Antimicrobial Use Surveillance measure and an Antimicrobial Resistance Surveillance measure beginning with the electronic health record (EHR) reporting period in CY 2025; (4) to modify the Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period; (5) to increase the total number of eCQMs reported from six to nine for the CY 2026 reporting period and then from nine to eleven beginning with the CY 2027 reporting period; and (6) to increase the minimum scoring threshold from 60 points to 80 points beginning with the EHR reporting period in CY 2025.

As shown in the summary table in section XII.B.9. of this proposed rule, we estimate a total information collection burden increase for 3,150 eligible hospitals and 1,400 CAHs of 5,038 hours at a cost of $262,581 annually associated with our proposed policies and updated burden estimates over the three-year period from the EHR reporting period in CY 2025 through the EHR reporting period in CY 2027 compared to our currently approved information collection burden estimates. We refer readers to section XII.B.9.f. of the preamble of this proposed rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

In section IX.F.6.a. of the preamble of this proposed rule, we are proposing to adopt two new eCQMs and to modify one eCQM. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to the proposed policies with regard to submission of measure data, we believe that costs associated with adopting two new eCQMs and modifying one existing eCQM are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining all of the eCQMs available for use in the Medicare Promoting Interoperability Program in hospitals' and CAHs' EHR systems (83 FR 41771).

In section IX.F.5. of the preamble of this proposed rule, we are proposing to increase the performance-based scoring threshold for eligible hospitals and CAHs reporting under the Medicare Promoting Interoperability Program from 60 points to 80 points beginning with the EHR reporting period in CY 2025. Our review of the CY 2022 Medicare Promoting Interoperability Program's performance results indicates 98.5% of eligible hospitals and CAHs currently successfully meet the threshold of 60 points while 81.5% of eligible hospitals and CAHs currently exceed a score of 80

points. If this proposal is finalized, the 17% of eligible hospitals and CAHs that meet the current threshold of 60 points but not the proposed threshold of 80 points would be required to better align their health information systems with evolving industry standards and/or increase data exchange to raise their performance score or be subject to a potential downward payment adjustment. We do not believe the remaining proposed policies would result in any additional economic impact beyond the additional collection of information burden discussed in section XII.B.9. of the preamble of this proposed rule.

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered for the Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)

Section 4122(a) of the CAA, 2023 amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of an additional 200 residency positions (also referred to as slots) to qualifying hospitals. Section 1886(h)(10)(B)(iii) of the Act further requires that each qualifying hospital that submits a timely application receive at least 1 (or a fraction of 1) of the slots made available under section 1886(h)(10) of the Act before any qualifying hospital receives more than 1 residency position.

In section V.F.2. of this proposed rule we discuss our proposal to first distribute slots by prorating the available 200 positions among all qualifying hospitals such that each qualifying hospital receives up to 1.00 FTE—that is, 1.00 FTE or a fraction of 1.00 FTE. We are proposing that a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories, as defined at section 1886(h)(10)(F)(iii) of the Act.[890] We are proposing that if any residency slots remain after distributing up to 1.00 FTE to each qualifying hospital, we will prioritize the distribution of the remaining slots based on the HPSA score associated with the program for which each qualifying hospital is applying using the methodology we finalized for purposes of implementing section 126 of the CAA, 2021 (86 FR 73434 through 73440). Using this HPSA prioritization method, we are proposing to limit a qualifying hospital's total award under section 4122 of the CAA, 2023, to 10.00 additional FTEs, consistent with section 1886(h)(10)(C)(i) of the Act.

We are considering an alternative approach to distributing the 200 residency slots under section 4122 of the CAA, 2023, which would place greater emphasis on the distribution of additional residency positions to hospitals that are training residents in geographic and population HPSAs. Under this approach, the statutory requirement that each qualifying hospital receive 1 slot or a fraction of 1 slot would be met by awarding each qualifying hospital 0.01 FTE. The remaining residency slots would be prioritized for distribution based on the HPSA score associated with the program for which each hospital is applying using the HPSA prioritization methodology we finalized for purposes of implementing section 126 of the CAA, 2021 (86 FR 73434 through 73440). To illustrate, if 1,000 qualifying hospitals were to apply under section 4122 of the CAA, 2023, we would first award each qualifying hospital 0.01 FTEs, resulting in the distribution of 10.00 FTEs (1,000 x 0.01). We would then distribute the remaining 190 slots (200 − 10) based on the HPSA prioritization method we finalized for implementation of section 126 of the CAA, 2021, such that applications associated with higher HPSA scores would receive priority. We believe that under this alternative distribution methodology we would further the work achieved by section 126 of the CAA, 2021, by distributing residency slots to underserved areas in greatest need of additional physicians. Using this alternative distribution methodology, we would limit a qualifying hospital's total award under section 4122 of the CAA, 2023, to 10.00 additional FTEs consistent with section 1886(h)(10)(C)(i) of the Act. Consistent with the methodology we use for implementation of section 126 of the CAA, 2021, as part of determining eligibility for additional slots, we would compare the hospital's FTE resident count to its adjusted FTE resident cap on the cost report worksheets submitted with its application. If the hospital's FTE count is below its adjusted FTE cap, the hospital would be ineligible for its full FTE request. We note that in calculating the adjusted FTE cap we do not consider adjustments for Medicare GME Affiliation Agreements, since these adjustments are temporary. We seek comment on this alternative proposal, including awarding each qualifying hospital 0.01 FTEs and use of HPSA scores to determine priority for remaining slots.

2. Alternative Considered for the Proposed Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

As discussed in section V.J. of the preamble of this proposed rule, we are proposing a separate payment to hospitals for the IPPS share of the additional costs of establishing and maintaining access to a 6-month buffer stock of one or more essential medicines, either directly or through contractual arrangement with pharmaceutical manufacturers, distributors, or intermediaries. Eligibility for payment under this proposed policy would be limited to small, independent hospitals with 100 or fewer beds that are not part of a chain organization. As also discussed in section V.J. of the preamble of this proposed rule, this proposal was informed by commenter feedback on the Request for Comment on a potential Medicare payment policy that would provide separate payment for Medicare's share of the inpatient costs of establishing and maintaining a 3-month buffer stock of one or more essential medicines for all IPPS hospitals, included in the CY 2024 OPPS/ASC proposed rule (88 FR 49867).

As part of a broader HHS initiative to address the detrimental effects of drug shortages, our intention with this proposed payment policy is to help insulate small, independent hospitals, and the inpatient care they provide, from the negative effects of drug shortages and promote the overall resiliency of drug supply chains without exacerbating existing shortages or contributing to hoarding behaviors for essential medicines during active shortages. As discussed in section V.J. of the preamble of this proposed rule, the appropriate time to establish a buffer stock for a drug is before it goes into shortage or after a shortage period has ended. In order to further mitigate any potential for the proposed policy to exacerbate existing shortages or contribute to hoarding, if an essential medicine is listed as ''Currently in Shortage'' on the FDA Drug Shortages Database, we are proposing that no separate buffer stock payment for that medicine would be made unless the hospital had already established and was maintaining a buffer stock of that medicine prior to the shortage. We believe that this approach is necessary to avoid rewarding hoarding behaviors, which we believe are not consistent with resiliency goals. If an essential medicine is listed as ''Currently in Shortage'' on the FDA Drug Shortages Database, we are proposing that a hospital that newly establishes a buffer stock of that medicine while it is in shortage would not be eligible for separate buffer stock payment for that medicine for the duration of the shortage. However, if a hospital had already established and was maintaining a buffer stock of that medicine prior to the shortage, we are proposing that the hospital would continue to be eligible for separate buffer stock payment for that medicine for the duration of the shortage. We are proposing that hospital would continue to be eligible even if the number of months of supply of that medicine in the buffer stock were to drop to less than 6 months as the hospital draws down that buffer stock. Once an

[890] Category One consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or have been reclassified being located in a rural area (pursuant to section 1886(d)(8)(E) of the Act). Category Two consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(10)(F)(iv) of the Act) is greater than the otherwise applicable resident limit. Category Three consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME) or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). Category Four consists of hospitals that serve areas designated as HPSAs under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary.

essential medicine is no longer listed as ''Currently in Shortage'' in the FDA Drug Shortages Database, our proposed policy does not differentiate that essential medicine from other essential medicines and hospitals would be eligible to establish and maintain buffer stocks for the medicine as they would have before the shortage.

We also considered an alternative to this policy whereby a hospital would no longer be eligible for separate payment for the buffer stock of an essential medicine beginning on the day the medicine is listed as ''Currently in Shortage'' on the FDA Drug Shortages Database, even if the hospital had already established and was maintaining a buffer stock of that medicine prior to the shortage. Under this alternative approach, the separate payment would not be available for the portion of the cost reporting period during which the medicine is listed on the FDA Drug Shortages Database. However, as this separate payment is proposed to be limited to small, independent hospitals, we do not believe such an approach is necessary, as we do not believe these hospitals would have the ability to continue to acquire essential medicines for their buffer stocks during an active shortage the way that larger hospitals and chain hospitals may be able to do. If we proposed different hospital eligibility requirements, including larger hospitals or chain hospitals that have greater ability to continue to acquire and potentially hoard an essential medicine in active shortage, we would likely have proposed to limit eligibility for separate payment for the buffer stock during a given cost reporting period in this alternative manner. We were also concerned about the potential administrative burden of record keeping and additional monitoring of the FDA Drug Shortages Database on these small, independent hospitals if this alternative policy was proposed.

We also considered whether a certain period of time, 6 months for example, should elapse before an essential medicine that was listed as ''Currently in Shortage'' on the FDA Drug Shortages Database would become eligible for separate payment for the additional resource costs of establishing and maintaining a 6-month buffer stock. Had we proposed different hospital eligibility requirements for the separate payment, including larger hospitals or chain hospitals as mentioned previously, we may have proposed such a requirement to account for the ramp up time that manufacturers need to reestablish supply of a given drug in shortage and to not reward potential hoarding behaviors. Because the buffer stocks that small, independent hospitals would require are likely smaller compared to larger hospitals and hospital chains, we do not believe that these hospitals would induce substantial demand shocks in the pharmaceutical supply chain through establishing their respective buffer stocks of essential medicines immediately following an active shortage of an essential medicine. Therefore, we do not believe it is necessary to require that a certain period of time should elapse after an essential medicine is no longer listed as ''Currently in Shortage'' before that medicine becomes eligible for separate payment under our proposed policy.

As discussed in section V.J. of the preamble of this proposed rule, we are proposing that for purposes of the proposed separate payment under the IPPS, the costs of buffer stocks that would be eligible for separate payment are the additional resource costs of establishing and maintaining access to a 6-month buffer stock for any eligible medicines on ARMI's List of 86 essential medicines, including any subsequent revisions to that list of medicines. We are proposing that if the ARMI List is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment under this policy for the IPPS shares of the costs of establishing and maintaining access to 6-month buffer stocks as of the date the updated ARMI List is published. However, we recognize that the ARMI List does not include certain medicines that have recently been in shortage and that may be considered essential and are more prevalent in specific care settings other than an inpatient hospital, such as drugs used in oncology care on an outpatient basis. We considered providing separate payment under this proposal for establishing and maintaining access to a buffer stock of a broader list of medicines than just those on the ARMI List, for example, to include certain types of oncology drugs. To the extent that in the future other lists or medicines (such as buprenorphine-based medications or oncology drugs) are identified for eligibility in future iterations of this policy, we are seeking comment on the potential mechanism and timing for incorporating those updates.

3. Alternatives Considered to the LTCH QRP Reporting Requirements

With regard to the proposal to add three assessment items to the LCDS and replace one assessment item on the LCDS, we believe these proposals will advance the CMS National Quality Strategy Goals of equity and engagement. We considered the alternative of delaying the proposal to collect these assessment items, but given the fact they will encourage meaningful collaboration between healthcare providers, caregivers, and community-based organizations to address HRSNs prior to discharge from the LTCH, we believe further delay is unwarranted. With regard to the proposal to extend the LCDS Admission assessment window, we considered the option of maintaining the current 3-day assessment period versus extending it to 4 days. However, this proposal is responsive to providers' feedback we received regarding the difficulty of collecting the required LCDS data elements within the 3-day assessment window when medically complex patients are admitted prior to and on weekends. Additionally, extending the assessment period would have no impact on the calculation of LTCH QRP measures, and would only require minimal revisions to the LCDS guidance manuals.

4. Alternatives Considered for the FY 2025 LTCH PPS Outlier Fixed-Loss Threshold

As discussed in section V.D.3. of the Addendum of this proposed rule, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 of $90,921 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2025 payments for such cases. We acknowledge that the proposed increase to the fixed-loss amount from the FY 2024 fixed-loss amount ($59,873) is substantial. We also acknowledge that the FY 2024 fixed-loss amount was substantially higher than the FY 2023 fixed-loss amount ($38,518). We recognize that such substantial increases to the fixed-loss amount in consecutive years could impact LTCH operations.

For this reason, as an alternative to our proposed fixed-loss threshold, using the broad authority conferred upon the Secretary under section 307(b)(1) of the BIPA to make ''adjustment'' to ''outliers'' under the LTCH prospective payment system, we considered proposing to establish the FY 2025 fixed-loss amount as an average of the FY 2024 fixed-amount ($59,873) and our modelled FY 2025 fixed-loss amount ($90,921). Under this approach, the proposed fixed-loss amount would have been $75,397 (($59,873 + $90,921)/2). This alternative approach would provide a 1-year transition to the full increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases that we project would result in estimated outlier payments projected to be equal to 7.975 percent of estimated payments for such cases.

We estimate that this alternative fixed-loss amount would result in estimated outlier payments projected to be equal to 9.5 percent of estimated FY 2025 payments for such cases. Under this approach, the estimated difference between the 7.975 percent target and the estimated percentage of outlier payments under the alternative fixed-loss amount would be non-budget neutral. As we have previously stated in the RY 2007 LTCH PPS final rule (71 FR 27863 through 27864) and most recently in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59426), we believe that the mandate in section 123(a)(1) of the BBRA for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). We estimate that aggregate FY 2025 LTCH PPS payments would increase by $39 million under this alternative approach, based on the data used in this proposed rule. We are soliciting comments on both our proposed methodology for determining the FY 2025 fixed-loss amount discussed in section V.D.3. of the Addendum of this proposed rule and the alternative approach discussed in this section. We will consider these comments when finalizing the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 in the final rule.

5. Alternatives Considered for the Transforming Episode Accountability Model

In section X.A. of the preamble of this proposed rule, we are proposing to test a new mandatory episode-based payment model called the Transforming Episode Accountability Model (TEAM). TEAM is designed to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM would test whether financial accountability

for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM would benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. For example, we considered allowing physician group practices (PGPs) be TEAM participants, however, we are concerned that PGPs are generally smaller entities and care for a lower volume of Medicare beneficiaries which could make it challenging to take on the level of financial risk to participate in the model. We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider. We note that our estimates are limited to acute care hospitals that may be selected to participate in this proposed model. This proposed model would not directly affect hospitals that are not participating in the model. However, the model may encourage innovations in health care delivery in other areas or in care reimbursed through other payers. For example, a TEAM participant may choose to extend their arrangements to arrangements outside of the model for all surgical procedures they provide, as permitted by all applicable laws, not just those reimbursed by Medicare and tested in TEAM. We welcome comments on our proposals and the alternatives we have identified in the preamble.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $3.2 billion in FY 2025, including operating, capital, and the combined effects of (1) the proposed changes to add-on payments for certain ESRD discharges, (2) the proposed payment adjustment for establishing and maintaining access to a buffer stock of essential medicines, (3) new technology add-on payment changes, and (4) the statutory expiration of the MDH program and the temporary changes to the low-volume hospital payment adjustment on January 1, 2025. The estimated change in operating payments is approximately $3.1 billion (discussed in sections I.F of this Appendix). The estimated change in capital payments is approximately $0.183 billion (discussed in section I.I. of this Appendix). The estimated change in the combined effects of (1) the proposed changes to add-on payments for certain ESRD discharges, (2) the proposed payment adjustment for establishing and maintaining access to a buffer stock of essential medicines, (3) new technology add-on payment changes, and (4) the statutory expiration of the temporary changes to the low-volume hospital payment adjustment on January 1, 2025 is approximately −$0.158 billion as discussed in sections I.F and I.G. of this Appendix. Totals may differ from the sum of the components due to rounding.

Table I. of section I.F. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and proposed wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals will experience a 2.4 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there will be a $183 million increase in capital payments in FY 2025 compared to FY 2024.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2025. In the impact analysis, we are using the rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2025. Accordingly, based on the best available data for the 330 LTCHs included in our analysis, we estimate that overall FY 2025 LTCH PPS payments would increase approximately $41 million relative to FY 2024, primarily due to the proposed annual update to the LTCH PPS standard Federal rate partially offset by an estimated decrease in high-cost outlier payments.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 3,274 number of timely pieces of correspondence on the FY 2024 IPPS/LTCH proposed rule as our estimate for the number of reviewers of this rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $100.80 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 20.83 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $2,099.66 (20.83 hours × $100.80). Therefore, we estimate that the total cost of reviewing this proposed rule is $6,874,299.94 ($2,099.66 × 3,274 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies in this proposed rule are estimated at $3.2 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2024 TO FY 2025

Category	Transfers
Annualized Monetized Transfers	$3.2 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2025 relative to FY 2024 of approximately $41 million based on the data for 330 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate LTCHs. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this proposed rule based on the data for the 330 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $41 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2024 LTCH PPS TO THE FY 2025 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$41 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this proposed rule relating to IPPS hospitals would have an economically significant impact on small entities as explained in this Appendix. Therefore, the Secretary has certified that this proposed rule would have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,090 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2025,'' on average are expected to see increases in the range of 2.4 percent, primarily due to the proposed hospital rate update, as discussed in section I.F. of this Appendix. On average, the proposed rate update for these hospitals is estimated to be 2.4 percent.

The 330 LTCH PPS hospitals included in the impact analysis shown in ''Table IV: Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2025 (Estimated FY 2024 Payments Compared to Estimated Proposed FY 2025 Payments)'' on average are expected to see an increase of approximately 1.2 percent, primarily due to the proposed annual standard Federal rate update for FY 2025 (2.8 percent) being partially offset by a projected 1.3 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

This proposed rule contains a range of proposals. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this Appendix and throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. We are seeking public comments on our estimates and analysis of the impact of our proposals on small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.F. of this Appendix, rural IPPS hospitals with 0–49 beds (350 hospitals) are expected to experience an increase in payments from FY 2024 to FY 2025 of 0.7 percent and rural IPPS hospitals with 50–99 beds (183 hospitals) are expected to experience no change in payments from FY 2024 to FY 2025. These changes are primarily driven by the proposed hospital rate update offset by the statutory expiration of the MDH program. We refer readers to Table I. in section I.F. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.

All rural LTCHs (18 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are

expected to experience an increase in payments from FY 2024 to FY 2025 of 2.3 percent. This increase is primarily due to the combination of the proposed 2.8 percent annual update to the LTCH PPS standard Federal payment rate for FY 2025, the proposed changes to the area wage level adjustment, and estimated changes in outlier payments, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold level is approximately $183 million. This proposed rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act. We continue to engage in consultations with Tribal officials on IPPS issues of interest. We will use input received from these consultations, as well as the comments on the proposed rule, to inform this rulemaking.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2025, consistent with our approach for FY 2024, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2025

A. Proposed FY 2025 Inpatient Hospital Update

As discussed in section V.B. of the preamble to this proposed rule, for FY 2025, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In this FY 2025 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2025 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2023, which is estimated to be 3.0 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this FY 2025 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2023 forecast, we are proposing a productivity adjustment of 0.4 percentage point for FY 2025. We are also proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2025 market basket update and productivity adjustment for the FY 2025 IPPS/LTCH PPS final rule.

Therefore, based on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket update and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

B. Proposed FY 2025 SCH and MDH Update

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2025 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

Section 307 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program for FY 2025 discharges occurring before January 1, 2025. Prior to enactment of the CAA, 2024, the MDH program was only to be in effect through the end of FY 2024. Therefore, under current law, the MDH program will expire for discharges on or after January 1, 2025. We refer readers to section V.E. of the preamble of this proposed rule for further discussion of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2025 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section V.B.1. of the preamble of this proposed rule.

In addition, as discussed in section V.B.2. of the preamble of this proposed rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that for FY 2024 and subsequent fiscal years, any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments).

Based on IGI's fourth quarter 2023 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2023, for this FY 2025 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing a market basket update of 3.0 percent and a productivity adjustment of 0.4 percentage point. Therefore, for FY 2025, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing the following applicable percentage increases to the standardized amount for FY 2025 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 2.6 percent (that is, the FY 2025 estimate of the proposed market basket rate-of-increase of 3.0 percent less an adjustment of 0.4 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 0.35 percent (that is, the FY 2025 estimate of the proposed market basket rate-of-increase of 3.0 percent, less an adjustment of 2.25 percentage point (the proposed market basket rate-of-increase of 3.0 percent × 0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.4 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2025 market basket update and the productivity adjustment for the FY 2025 IPPS/LTCH PPS final rule.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2025

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, we are proposing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2025 and subsequent fiscal years. Accordingly, for FY 2025, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2025 percentage increase in the 2018-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket

percentage increase for FY 2025 is 3.0 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2025 market basket update for the FY 2025 IPPS/LTCH PPS final rule.

E. Proposed Update for LTCHs for FY 2025

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2025 by 2.8 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCH QR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.028 in determining the LTCH PPS standard Federal rate for FY 2025. For LTCHs that fail to submit quality data for FY 2025, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.8 percent (that is, the proposed annual update for FY 2025 of 2.8 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.008 in determining the LTCH PPS standard Federal rate for FY 2025. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.8 percent for FY 2025 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law plus 1.5 percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.0 percent.

For FY 2025, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.8 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2025, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.8 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2024 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law plus 1.5 percent. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law plus 1.5 percent in 2025 would generally be adequate to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to, if somewhat below, the cost of delivering high-quality care efficiently.

MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1.5 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends adding $4 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

We refer readers to the March 2024 MedPAC report, which is available for download at *www.medpac.gov,* for a complete discussion on these recommendations.

We are proposing an applicable percentage increase for FY 2025 of 2.6 percent as described in section 1886(b)(3)(B) of the Act, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

We note that section 1886(d)(5)(F) of the Act provides for additional Medicare payment adjustments, called Medicare disproportionate share hospital (DSH) payments, for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 1886(r) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay each such subsection (d) hospital that is eligible for Medicare DSH payments an empirically justified DSH payment equal to 25 percent of the Medicare DSH adjustment they would have received under section 1886(d)(5)(F) of the Act if subsection (r) did not apply. The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments if subsection (r) of the Act did not apply, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and has uncompensated care. These additional payments are called uncompensated care payments. We refer readers to section IV. of this proposed rule for a further discussion of Medicare DSH and uncompensated care payments.

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